To Register for the Drug Price Transparency Reporting

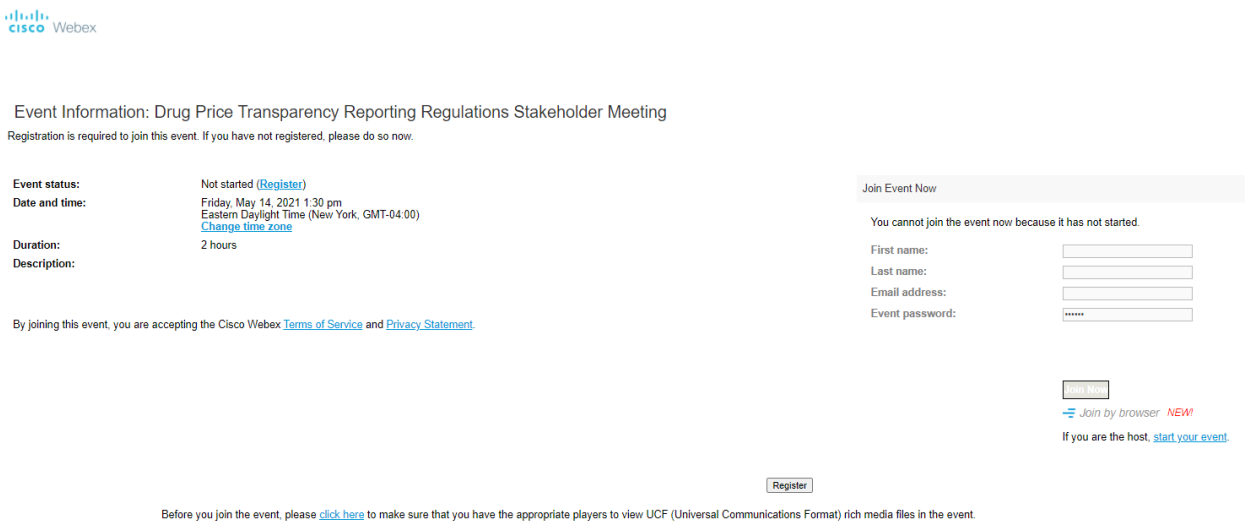
Regulations Stakeholder Meeting on May 14, 2021

(Either to attend and view the meeting or to speak during the Public Comment Period)

The purpose of these instructions is to help any member of the public who wishes to observe or participate in the Drug Price Transparency Reporting Regulations Stakeholder Meeting on May 14 to understand how to do so. Please note that while the screenshots may not be for the Drug Price Transparency Reporting Regulations Stakeholder May 14 meeting, the instructions are the same.

1) Open the link the Online meeting registration:

   https://covaconf.webex.com/covaconf/onstage/g.php?MTID=e6012e11af71f6938b7f56efa8cef4870



2) Click on the link that says, “Register” It is in blue and on the line that starts with “Event Status”.

Event Information: Drug Price Transparency Reporting Regulations Stakeholder Meeting

Registration is required to join this event. If you have not registered, please do so now.

Event status: Not started (Register)

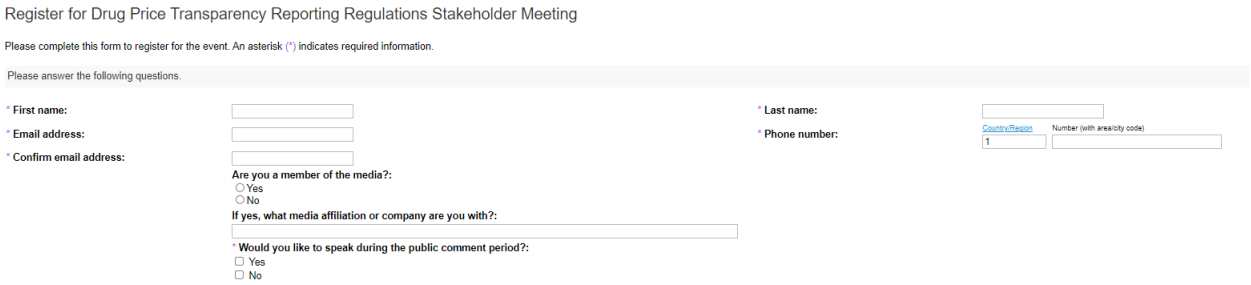
Date and time: Friday, May 14, 2021 1:30 pm
Eastern Daylight Time (New York, GMT-04:00)
Change time zone

Duration: 2 hours

Description:

By joining this event, you are accepting the Cisco Webex Terms of Service and Privacy Statement.

3) This will prompt you to register for the event. Please enter your name and email address on the registration form. (Note: this information will not be retained after the meeting and will only be used for purposes of making sure people who want to connect to the meeting or speak at the meeting can do so.)



Register for Drug Price Transparency Reporting Regulations Stakeholder Meeting

Please complete this form to register for the event. An asterisk (*) indicates required information.

Please answer the following questions.

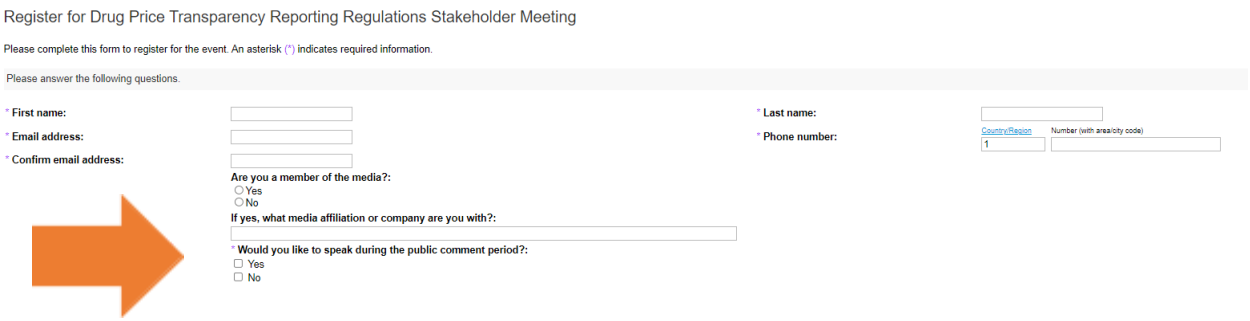
* First name:
* Last name:
* Email address:
* Phone number: Country/Region 1 Number (with area/city code)
* Confirm email address:

Are you a member of the media?:
Yes
No

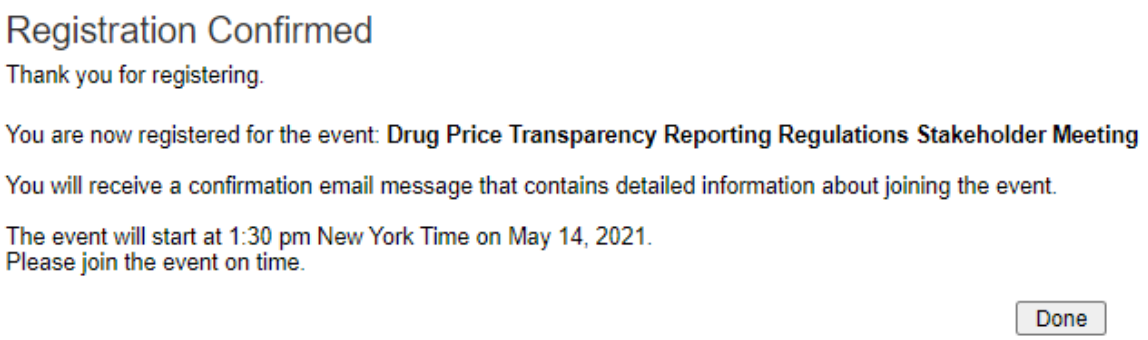
If yes, what media affiliation or company are you with?:

* Would you like to speak during the public comment period?:
Yes
No

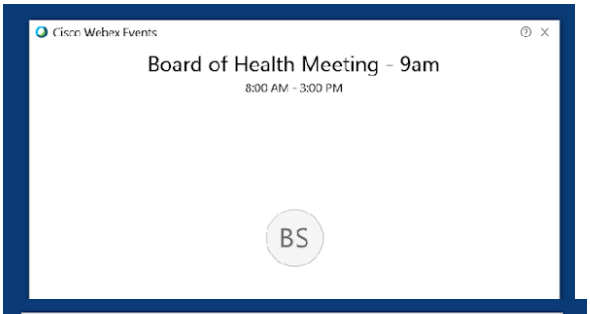
4) If you want to speak during the public comment, please indicate the topic area you would like to speak on. If you do not want to speak during the meeting, but just watch, please check no on the public comment question. When you are finished entering registration information and choosing a topic to speak on (if appropriate) click the “Submit” button in the bottom right.



5) Once you have clicked “Submit” that will lead you to the final screen and then you are finished.

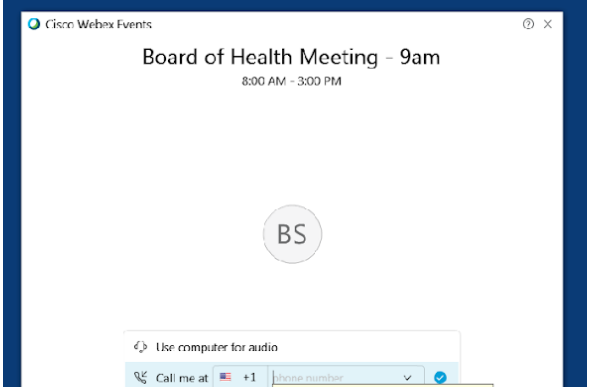


JOINING THE MEETING



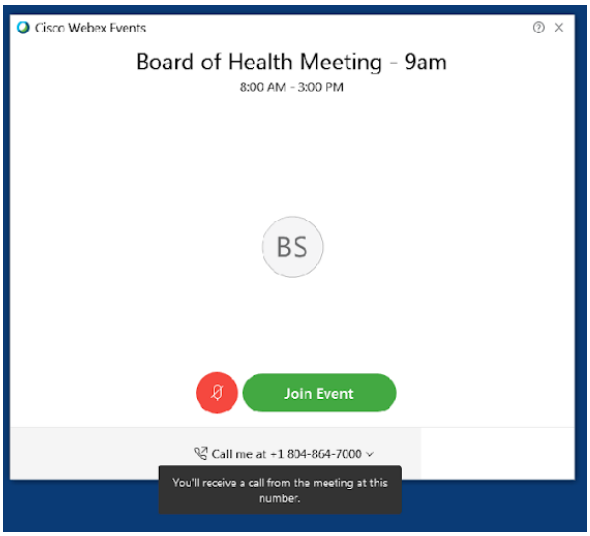
On the day of the meeting, you will click in the email to join the meeting.

You will need to enter your name as it appeared on the registration in order to join.



You should select the “CALL ME AT” option to connect for audio. DO NOT select the call in nor use computer audio options.

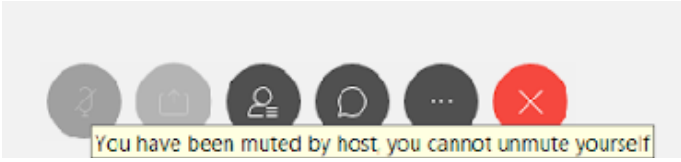
Enter your 10 digit phone number and click the blue check mark.



Click Join Event.

You will receive a phone call from the meeting platform.

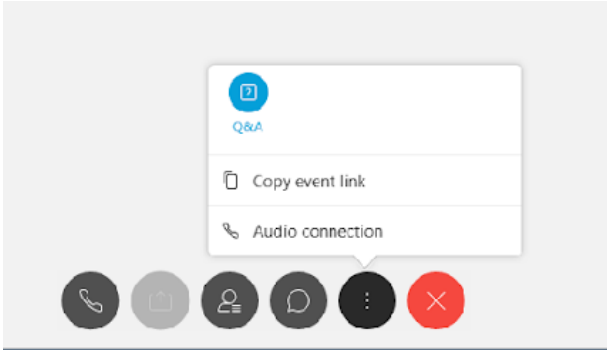
You will be prompted to press 1 when you answer the phone to connect.



Note that you will be automatically muted when you join the meeting. You cannot unmute yourself to be heard during the meeting until the host unmutes you. This will occur during the public comment period for those who have signed up to do so.

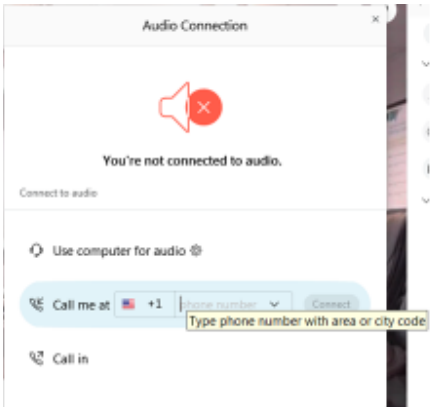
Audio settings:

In order to facilitate public comment, you will need to use your phone to dial in. It is very important that you follow these instructions to merge your phone and computer identification. This will allow you to be unmuted to speak during public comment if you have signed up.



If you have joined the meeting without having WebEx call you, you will need to change the audio settings. Click on the "MORE" control button and select audio connection. **DO NOT** use the call-in

option nor the computer audio option.



You will change the type of connection and select “CALL ME AT”. Enter your 10 digit phone number and click CONNECT. Press 1 when prompted on the incoming phone call.

Drug Price Transparency Reporting Regulations
Stakeholder Meeting
Agenda
May 14, 2021 - 1:30pm
VIA WEBEX

The public may sign up to virtually attend through
https://covaconf.webex.com/covaconf/onstage/g.php?MTID=e6012e11af71f6938b7f56efa8cef4870

Call to Order	Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs, Virginia Department of Health
Welcome and introductions	Mr. Hilbert
Initial stakeholder feedback	Stakeholder Participants
Public Comment Period	
Section by Section Review of Draft Regulations	VDH staff and stakeholders
Next Steps	Mr. Hilbert
Adjourn	

12VAC5-219 Prescription Drug Price Transparency Regulation

Part I. General Information and Requirements

12VAC5-219-10. Definitions

The following words and terms when used in this chapter have the following meanings unless the context clearly indicates otherwise:

“Biologic” means a therapeutic drug, made from a living organism such as human, animal, yeast or microorganisms, which is licensed under a Biologic License Application by the FDA.

“Biosimilar” has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.

“Board” means the State Board of Health.

“Brand-name drug” has the same meaning as ascribed to the term in §§ 54.1-3436.1 and 54.1-3442.02 of the Code of Virginia.

“Carrier” has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.

“Commissioner” means the State Health Commissioner.

“Cost” means the expense incurred and the monetary value of the resources used or consumed in the production or provision of a prescription drug, biologic, or biosimilar by a reporting entity.

“Course of treatment” means the total dosage of a drug that would be prescribed in a single prescription to a patient taking the drug as recommended by its prescribing label as approved by the FDA. If there is more than one such recommended dosage, the largest recommended total dosage will be considered for purposes of determining a course of treatment.

“Department” means the State Department of Health.

“Discount” means any reduction in the price of a prescription drug, biologic, or biosimilar offered or provided by a reporting entity, including point-of-purchase or point-of-sale consumer coupons and copay assistance.

“Drug product” means a finished dosage form, such as a tablet or solution, that contains a prescription generally, but not necessarily, in association with inactive ingredients and that has been issued a National Drug Code by the FDA.

“Enrollee” has the same meaning as ascribed to the term in § 38.2-3407.10 of the Code of Virginia.

“FDA” means the U.S. Food and Drug Administration.

“Generic drug” has the same meaning as ascribed to the term in § 54.1-3436.1 of the Code of Virginia.

“Health benefits plan” has the same meaning as ascribed to the term in § 38.2-3438 of the Code of Virginia.

“Health care services” has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.

“Health plan” has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.

“Launched” means the month and year on which a manufacturer acquired or first marketed a prescription drug, biologic or biosimilar for sale in the United States.

“Manufacturer” has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.

“New prescription drug” has the same meaning as ascribed to the term in § 54.1-3442.02 of the Code of Virginia.

“Nonprofit data services organization” or “NDSO” has the same meaning as ascribed to the term in § 32.1-23.3 of the Code of Virginia.

“Outpatient prescription drug” means a prescription drug that may be obtained only by prescription and dispensed by a retail or outpatient pharmacy. Outpatient prescription drug excludes prescription drugs provided as part of or incident to and in the same setting as inpatient and outpatient hospital services, hospice services, dental services, nursing home and intermediate care facility services, and physician services (e.g., physician-administered drugs).

“Pharmacy benefits management” had the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.

“Pharmacy benefits manager” or “PBM” has the same meaning as ascribed to the term in § 38.2-3407.15:4 of the Code of Virginia.

“Premium” means the amount members pay to a carrier or health plan for their medical and prescription drug insurance.

“Price” means the amount of money an individual consumer pays at retail for a drug, biologic, or biosimilar in the absence of a discount, rebate, or price concession.

“Prescription drug” has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.

“Rebate” has the same meaning as ascribed to the term in § 38.2-3407.22 of the Code of Virginia.

"Reporting entity" means carriers, PBMs, wholesale distributors, and manufacturers.

"SEC" means the U.S. Securities and Exchange Commission.

"Specialty drug" means a drug that is costly, requires special supply chain features such as freezing or cold storage, is typically indicated for a small group of patients, and where the patients may need special case management services

"Spending" means the amount of money, expressed in U.S. dollars, expended.

"Therapeutically equivalent" means a generic drug that:

1. Is approved as safe and effective;
2. Is pharmaceutical equivalent to a brand-name drug in that it:
    a. Contains identical amounts of the identical active drug ingredient in the identical dosage form and route of administration; and
    b. Meets compendial or other applicable standards of strength, quality, purity, and identity;
3. Is bioequivalent to a brand-name drug in that:
    a. It does not present a known or potential bioequivalence problem, and they meet an acceptable *in vitro* standard; or
    b. If it does present such a known or potential problem, it is shown to meet an appropriate bioequivalence standard;
4. Is adequately labeled; and
5. Is manufactured in compliance with 21 CFR Part 210, 21 CFR Part 211, and 21 CFR Part 212.

"Utilization management" means strategies, including drug utilization review, prior authorization, step therapy, quantity or dose limits, and comparative effectiveness reviews to reduce a patient's exposure to inappropriate drugs and lower the cost of treatment.

"Wholesale acquisition cost" or "WAC" has the same meaning as ascribed to the term in §§ 54.1-3436.1 and 54.1-3442.02 of the Code of Virginia.

"Wholesale distributor" has the same meaning as ascribed to the term in § 54.1-3401 of the Code of Virginia.

"30-day supply" means the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days. If there is more than one such recommended daily dosage, the largest recommended daily dosage will be considered for purposes of determining a 30-day supply.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-219-20. Registration

A. Each reporting entity shall furnish to and maintain with the department and the NDSO:
    1. Its legal name and any fictitious names under which it operates;
    2. Its current mailing address of record; and
    3. Its current electronic address of record.
B. The reporting entity shall notify the department and the NDSO in writing of any change in its legal name or addresses of record within 30 calendar days of such change.
C. Each reporting entity shall notify the department and the NDSO of its business closing, discontinuation of business as a carrier, PBM, manufacturer, or wholesale distributor, or acquisition at least 30 days prior to such closure, discontinuation, or acquisition.
    1. A reporting entity shall file any report otherwise due on April 1 for the preceding calendar year pursuant to Part II (12VAC5-219-40 et seq.) of this chapter prior to its closure, discontinuation, or acquisition if the reporting entity plans or anticipated that between January 1 and April 1:
        a. Its business will close;
        b. Its business as a carrier, PBM, manufacturer, or wholesale distributor will be discontinued; or
        c. Its acquisition will result in the discontinuation of its business as a carrier, PBM, manufacturer, or wholesale distributor between.
    2. The business acquiring a reporting entity shall ensure that it complies with the provisions of this chapter.
    3. The commissioner shall deem the failure to comply with subdivision C 1 of this section as a failure to report pursuant to Part II (12VAC5-219-40 et seq.) of this chapter.

Statutory Authority
§ 32.1-12 of the Code of Virginia.

12VAC5-219-30. Notice

A. The NDSO shall send to the reporting entity at the last known electronic address of record:
    1. An annual notice on or before March 1 regarding its reporting obligations under Part II (12VAC5-219-40 et seq.) of this chapter. Failure to receive this notice does not relieve the reporting entity of the obligation to timely report; and
    2. Any notices pursuant to Article 1 (12VAC5-219-90 et seq.) of Part III of this chapter.
B. If the NDSO determines that it will accept alternate drug group system other than Medi-Span© for reports due pursuant to Part II (12VAC5-219-40 et seq.:
    1. The department shall publish a general notice in the Virginia Register that contains the NDSO's determination and the effective date of this determination; and.
    2. The NDSO shall notify every reporting entity of the NDSO's determination by electronic mail at its electronic address of record.

C. The department shall send notices pursuant to Part III (12VAC5-219-110 et seq.) of this chapter and case decisions to the last known electronic address of record and mailing address of record.
D. The NDSO shall provide any record requested by the board, the commissioner, or department related to the enforcement or administration of § 32.1-23.3 of the Code of Virginia or this chapter no more than 10 business days after the request, except as otherwise agreed to between the NDSO and the board, the commissioner, or department.

Statutory Authority
§ 32.1-12 of the Code of Virginia.

Part II. Reporting Requirements

12VAC5-219-40. Carrier reporting and contract requirements

A. Every carrier offering a health benefit plan shall report annually by April 1 to the NDSO on total annual spending on prescription drugs, before enrollee cost sharing, for each health benefit plan offered by the carrier in the Commonwealth.
B. For covered outpatient prescription drugs that were prescribed to enrollees during the immediately preceding calendar year, the carrier shall report:
    1. The names of the 25 most frequently prescribed outpatient prescription drugs, including supporting information for validation;
    2. 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, including supporting information for validation; and
    3. The names of the 25 outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated using the total annual spending by a health benefit plan for each outpatient prescription drug covered by the health benefit plan, including supporting information for validation.
C. In determining which outpatient prescription drugs are reportable under subsection B of this section, the carrier shall:
    1. Average the frequency of prescription for all drug products of an outpatient prescription drug to determine which outpatient prescription drugs are reportable under subdivision B 1;
    2. Average the cost, calculated using the total annual spending by such health benefit plan for all drug products of an outpatient prescription drug covered by the health benefit plan, to determine which outpatient prescription drugs are reportable under subdivision B 2; and
    3. Average the year-over-year increase in cost, calculated using the total annual spending by a health benefit plan for all drug products of an outpatient prescription drug covered by the health benefit plan, to determine which outpatient prescription drugs are reportable under subdivision B 3.

D. The carrier shall report for each outpatient prescription drug reportable under subsection B of this section, including every drug product of reportable outpatient prescription drug:
    1. The percent increase in annual net spending for prescription drugs after accounting for aggregated rebates, discounts, or other reductions in price;
    2. The percent increase in premiums that were attributable to each health care service, including prescription drugs;
    3. The percentage of specialty drugs with utilization management requirements; and
    4. The premium reductions that were attributable to specialty drug utilization management.

E. A carrier shall not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs when submitting a report pursuant to subsection A of this section.

F. Every carrier offering a health benefit plan shall require each PBM with which it enters into a contract for pharmacy benefits management to comply with 12VAC5-219-50.

G. Every carrier shall annually provide the information specified in subsection B to each PBM with which it enters into a contract for pharmacy benefits management no later than February 15.

H. Every carrier shall provide the information specified in subsection B and C of this section on a form prescribed by the board that includes the following data elements:

Data Element Name	Data Element Definition
Carrier tax identification number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).
Carrier name	The legal name of the reporting entity.
Proprietary drug name	The brand or trademark name of the drug reported to the FDA.
Non-proprietary drug name	The generic name assigned by the United States Adopted Names (USAN) Council.
National Drug Code	The numerical code maintained by the FDA that includes the labeler code, product code, and package code.
WAC unit	The lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
Drug group	The Medi-Span© Generic Product Identifier, which is numerical code issued by Medi-Span© that is 14 digits.

Brand-name drug or generic drug	Whether the drug is brand-name or generic.
Net spending increase	The percent year-over-year increase in annual net spending for prescription drugs after accounting for aggregated rebates, discounts, or other reductions in price.
Premium increase	The percent year-over-year increase in premiums that were attributable to each health care service, including prescription drugs.
Specialty drugs with utilization management	The percentage of specialty drugs with utilization management requirements.
Premium reductions	The percent year-over-year of premium reductions that were attributable to specialty drug utilization management.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-219-50. Pharmacy benefits managers reporting requirements

A. Every PBM providing pharmacy benefits management to a carrier shall report annually by April 1 to the NDSO the following information for each drug required for submission by each carrier as defined in 12VAC5-219-40 subsections B and C for each drug identified pursuant to subsection F of 12VAC5-219-40 by each carrier with which it enters into a contract for pharmacy benefits management :
   1. The aggregate amount of rebates received by the PBM;
   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.

B. Every PBM shall provide the information specified in subsection A of this section on a form prescribed by the board that includes the following data elements:

Data Element Name	Data Element Definition
PBM tax identification number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).
PBM name	The legal name of the reporting entity.

Total rebates	Total rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth.
Commercial insurance payer rebates	Total rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth, in total for this payer type.
Medicaid rebates, before federal and state rebates	Total rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth, in total for this payer type.
Medicare rebates	Total rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth, in total for this payer type.
Other payer rebates	Total rebates received or negotiated directly with the manufacturer in the last calendar year, for business in the Commonwealth, in total for this payer type.
Total rebates passed on	Total rebates passed on to all enrollees of a health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount in the last calendar year, for business in the Commonwealth.
Commercial insurance payer rebates passed on	Total rebates passed on to enrollees of a health benefit plan offered by a commercial insurance payer at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount in the last calendar year, for business in the Commonwealth.
Medicaid rebates passed on, before federal and state rebates	Total rebates passed on to enrollees of a health benefit plan offered by or under Medicaid at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-

	sharing amount in the last calendar year, for business in the Commonwealth.
Medicare rebates passed on	Total rebates passed on to enrollees of a health benefit plan offered by or under Medicare at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount in the last calendar year, for business in the Commonwealth.
Other payer rebates passed on	Total rebates passed on to enrollees of a health benefit plan offered by any other payer at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount in the last calendar year, for business in the Commonwealth.

Statutory Authority
§ 32.1-12 of the Code of Virginia.

12VAC5-219-60. Manufacturer reporting requirements

A. Every manufacturer shall report annually by April 1 to the NDSO on each of its:
    1. Brand-name drug and biologic, other than a biosimilar, with:
        a. A WAC of $100 or more for a 30-day supply or a single course of treatment; and
        b. Any increase of 15% or more in the WAC of such brand-name drug or biologic over the preceding calendar year;
    2. Biosimilar with an initial WAC that is not at least 15% less than the WAC of the referenced brand biologic at the time the biosimilar is launched; and
    3. Generic drug with a price increase that results in an increase in the WAC equal to 200% or more during the preceding 12-month period, when the WAC 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.
        a. For the purposes of subdivision A 3, a price increase is the difference between the WAC of the generic drug after increase in the WAC and the average WAC of such generic drug during the previous 12 months.

B. For each prescription drug, biologic, and biosimilar identified in subsection A of this section, including each drug product of a reportable prescription drug, biologic, and biosimilar, a manufacturer shall report:
    1. The name of the prescription drug, biologic, or biosimilar;
    2. Whether the prescription drug, biologic, or biosimilar is a brand name or generic;
    3. The effective date of the change in WAC;

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, biologics, and biosimilars approved by the FDA within the previous three calendar years;
6. The name of each of the manufacturer's prescription drugs, biologics, and biosimilars 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 WAC.
8. Supporting documentation required by the NDSO to validate all information required by this section

C. Every manufacturer shall provide the information specified in subsection B of this section on a form prescribed by the board that includes the following data elements:

Data Element Name	Data Element Definition
Proprietary drug name	The brand or trademark name of the drug reported to the FDA.
Non-proprietary drug name	The generic name assigned by the United States Adopted Names (USAN) Council.
National Drug Code	The numerical code maintained by the FDA that includes the labeler code, product code, and package code.
WAC unit	The lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
Medi-Span© Generic Product Identifier	The numerical code issued by Medi-Span© that is 14 digits.
Brand-name drug or generic drug	Whether the drug is brand-name or generic.
Manufacturer tax identification number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).
Manufacturer name	The legal name of the reporting entity.
Subject to generic competition	Whether the drug is subject to generic competition as of December 31 of the preceding calendar year.
Date of initial generic competition	The month and year of initial generic competition.
Therapeutically equivalent generic version	Whether there is a therapeutically equivalent generic version of the drug available as of December 31 of the

	preceding calendar year.
Date of initial availability of therapeutically equivalent generic version	The month and year of initial availability of therapeutically equivalent generic version.
Year of market introduction	The year of market introduction of the drug.
WAC at market introduction	The manufacturer's list price to wholesalers or direct purchasers in the United States at market introduction, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include discounts, rebates or reductions in price.
Current year minus one WAC	The manufacturer's list price in U.S. dollars per unit, to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include discounts, rebates or reductions in price.
Current year minus two WAC	The manufacturer's list price in U.S. dollars per unit, to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include discounts, rebates or reductions in price.
Effective date of change in WAC	The month and year that the WAC changed.
Justification for current-year WAC increase	The reason or reasons that the manufacturer increased the WAC of the drug or drug group, compared with last year.
Research and development costs	Aggregate, company-level research and development costs in U.S. dollars for the most recent year for which final audit data is available.
Year of research and development costs	The year in which final audit data is available.

D. To satisfy the reporting requirements of this section, a manufacturer may submit information and data that a manufacturer includes in its annual consolidation report on the SEC Form 10-K or any other public disclosure.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-219-70. Wholesale drug distributors reporting requirements

A. If the department determines that data received from health carriers, PBMs, and manufacturers is insufficient, the department may request wholesale distributors to report the information specific in subsection B of this section.
    1. The department shall publish a general notice in the Virginia Register that contains its determination, the request for wholesale distributors reporting, and the deadline for wholesale distributors to report pursuant to subsection B of this section.
    2. The NDSO shall notify every wholesale distributor of the department's determination and request by electronic mail at its electronic address of record.

B. If requested by the department pursuant to subsection A of this section and no more than 45 calendar days after the publication of the general notice pursuant to subdivision A 1 of this section, a wholesale distributor shall report for the 25 costliest prescription drugs dispensed, including each drug product of a reportable prescription drug:
    1. The WAC directly negotiated with a manufacturer in the last calendar year;
    2. The WAC directly negotiated with a manufacturer in the current calendar year;
    3. Aggregate total rebates, discounts, and price concessions directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth, in total; and
    4. Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, in total.

C. In determining which prescription drugs are reportable under subsection B of this section, the wholesale distributor shall average the cost for all drug products of a dispensed prescription drug.

D. Every wholesale distributor shall provide the information specified in subsection B of this section on a form prescribed by the board that includes the following data elements:

Data Element Name	Data Element Description
Wholesale distributor tax identification number	The 9-digit tax Taxpayer Identification Number (TIN) used by the Internal Revenue Service (IRS).
Wholesale distributor name	The legal name of the reporting entity.
Proprietary drug name	The brand or trademark name of the drug reported to the FDA.
Non-proprietary drug name	The generic name assigned by the United States Adopted Names (USAN) Council.
National Drug Code	The numerical code maintained by the FDA that includes the labeler code,

	product code, and package code.
WAC unit	The lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.
Medi-Span© Generic Product Identifier	The numerical code issued by Medi-Span© that is 14 digits.
Brand-name drug or generic drug	Whether the drug is brand-name or generic.
Current year minus one minimum WAC	Minimum WAC in U.S. dollars, for each drug for which the wholesale distributor has negotiated with a manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the Commonwealth.
Current year minus one maximum WAC	Maximum WAC in U.S. dollars, for each drug for which the wholesale distributor has negotiated with a manufacturer in the last calendar year, related to prescriptions under an insurance policy issued in the Commonwealth.
Current year minus two minimum WAC	Minimum WAC in U.S. dollars, for each drug for which the wholesale distributor has negotiated with a manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the Commonwealth.
Current year minus two maximum WAC	Maximum WAC in U.S. dollars, for each drug for which the wholesale distributor has negotiated with a manufacturer in the current calendar year, related to prescriptions under an insurance policy issued in the Commonwealth.
Total manufacturer rebates, discounts, and price concessions	Total rebates, discounts, and price concessions for each drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.
Total pharmacy discounts, dispensing fees, and other fees	Total discounts, dispensing fees, and other fees for each drug negotiated in the last calendar year with a pharmacy.

E. The board, the commissioner, the department, and the NDSO may not disclose:
    1. The identity of a specific wholesale distributor;
    2. The price charged for a specific prescription drug or class of prescription drugs; or
    3. The amount of any price concession, rebate, or fee provided for a specific prescription drug or class of prescription drugs.

Statutory Authority
§ 32.1-12 of the Code of Virginia.

12VAC5-219-80. Method of report submission

A. A reporting entity shall submit any report required by Part II (12VAC5-219-40 et seq.) of this chapter to the NDSO through the NDSO's online collection tool.
B. A reporting entity shall submit any required report by:
    1. Uploading electronic spreadsheet files, or other methods as determined by the NDSO, that include all required information for each report and that comply with the NDSO's Format and File Specifications for Submission of Prescription Drug Reports. Each reporting entity shall be notified at least 30 calendar days in advance of any change in the report collection method.

Statutory Authority
§ 32.1-12 of the Code of Virginia.

Part III. Enforcement

Article 1. Data Validation and Audits

12VAC5-219-90. Data validation; notification; response

A. The NDSO shall complete data validation no more than 90 calendar days after submission. The NDSO shall:
    1. Notify a reporting entity if the NDSO cannot validate the data submitted pursuant to a report required under Part II (12VAC5-219-40 et seq.) of this chapter;
    2. Send the notification specified in subdivision A 1 of this section no more than 3 business days after completion of the data validation to the reporting entity's email address of record;
    3. Identify the specific report and the data elements within the report that does not satisfy the standards; and
    4. Provide a copy of the notification to the commissioner at the same time it is sent to the reporting entity.
B. Each reporting entity notified under subsection A shall make changes necessary to correct the report within 30 calendar days of the notification.
C. If a reporting entity fails to correct the report within 30 calendar days:

1. The NDSO shall provide to the commissioner within 1 business day of the failure to correct:
    a. The copy of the original report submitted by the reporting entity;
    b. Any subsequent updated reports that the reporting entity may have filed; and
    c. Any correspondence between the NDSO and the reporting entity after the notification sent pursuant to subsection A of this section; and
2. The commissioner shall deem the failure to correct as a failure to report pursuant to Part II (12VAC5-219-40 et seq.) of this chapter.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-219-100. Audit; corrective action plan

A. A reporting entity shall include a signed, written certification of the accuracy of any notification or report to the NDSO. Reporting entities may certify the accuracy of their notification or report through the NDSO's online collection tool.

B. The NDSO may verify through an independent external audit the finalized data submitted by a reporting entity, provided that the NDSO provides notice to the reporting entity at its email address of record no fewer than 30 calendar days prior to initiating the audit. The reporting entity shall be responsible for the cost of any independent external audit initiated pursuant to this section.

C. The NDSO shall:
    1. Consider recommendations from the reporting entity as to the scope of the audit and the selection of the independent auditor; and
    2. Send a copy of the audit findings to the reporting entity no more than 5 business days after the conclusion of the audit at its email address of record.

D. If any deficiencies are found during the audit:
    a. The NDSO shall:
        i. Notify a reporting entity by providing a copy of the audit findings no more than 5 business days after completion of the audit to the reporting entity's email address of record;
        ii. Provide a copy of the notification to the commissioner at the same time it is sent to the reporting entity.
    b. The reporting entity shall prepare a written corrective action plan addressing each deficiency cited at the time of audit as specified in subsection E of this section.

E. The reporting entity shall submit to the NDSO and the commissioner a corrective action plan no more than 10 business days after receipt of the audit findings, and shall include in the corrective action plan:
    1. A description of the corrective action or actions to be taken for each deficiency and the position title of the employees to implement the corrective action;
    2. The deadline for completion of all corrective action, not to exceed 45 business days from the receipt of the audit findings; and

3. A description of the measures implemented to prevent a recurrence of the deficiency.

F. The reporting entity shall ensure that the person responsible for the validity of the corrective action plan signs, dates, and indicates their title on the corrective action plan.

G. The NDSO shall:

1. Notify the reporting entity if the NDSO determines any item in the corrective action plan is unacceptable;
2. Grant the reporting entity two opportunities to revise and resubmit a corrective action plan that the NDSO initially determines to be unacceptable. If the reporting entity revises and resubmits the corrective action plan, the revision is due to the NDSO and the commissioner no more than 15 business days after NDSO has notified the reporting entity pursuant to subdivision 1 of this subsection.

H. If a reporting entity fails to comply with the corrective action plan:

1. The NDSO shall provide to the commissioner any correspondence between the NDSO and the reporting entity after the notification sent pursuant to subsection D of this section; and
2. The commissioner shall deem the failure to comply as a failure to report pursuant to Part II (12VAC5-219-40 et seq.) of this chapter.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

Article 2. Administrative Process

12VAC5-219-110. Disciplinary action

A. A reporting entity may not violate the provisions of this chapter.

B. The commissioner may:

1. For each violation of this chapter:
   a. Refer the reporting entity for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or
   b. May petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the reporting entity pursuant to subsection B or C of § 32.1-27 of the Code of Virginia; or
2. For each violation of Part II (12VAC5-219-40 et seq.) of this chapter, levy a civil penalty upon the reporting entity as specified in subsection B of 12VAC5-219-110, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

C. Each day that a reporting entity fails to report in violation of this chapter is a separate and sufficient cause for imposition of disciplinary action. If a reporting entity knowingly submits false, inaccurate, or misleading data pursuant to the reporting requirements of this chapter, the commissioner shall deem that submission as a failure to report.

Statutory Authority

§§ 32.1-12, 32.1-20, 32.1-26, 32.1-27, and 32.1-23.3 of the Code of Virginia.

12VAC5-219-120. Civil penalty

A. The commissioner may reduce or waive the civil penalty imposed pursuant to this section, if he, in his sole discretion, determines that the violation was reasonable or resulting from good cause.

B. Except as provided in subsection A of this section, the commissioner shall levy a civil penalty upon the reporting entity in an amount of:

1. For the first offense:
    a. $500 the first day in which the reporting entity fails to report;
    b. $1,000 for the second day in which the reporting entity fails to report;
    c. $1,500 for the third day in which the reporting entity fails to report;
    d. $2,000 for the fourth day in which the reporting entity fails to report; and
    e. $2,500 for the fifth day and each subsequent day in which the reporting entity fails to report; and
2. For the second offense:
    a. $1,000 the first day in which the reporting entity fails to report;
    b. $1,750 for the second day in which the reporting entity fails to report; and
    c. $2,500 for the third and each subsequent day in which the reporting entity fails to report; and
3. For the third and all subsequent offenses, $2,500 for each day in which the reporting entity fails to report.

C. The commissioner shall deem the first day in which the reporting entity fails to report as:

1. April 2 for a reporting entity that fails to submit any information or documentation pursuant to 12VAC5-219-40, 12VAC5-219-50, or 12VAC5-219-60 or for a reporting entity that knowingly submits false, inaccurate, or misleading data pursuant to 12VAC5-219-40, 12VAC5-219-50, or 12VAC5-219-60;
2. The 46th calendar day after the publication of the general notice pursuant to subdivision A 1 of 12VAC5-219-70 for a wholesale distributor that that fails to submit any information or documentation or that knowingly submits false, inaccurate, or misleading data;
3. The 31st calendar day after notification pursuant to 12VAC5-219-90 for a reporting entity that fails to correct its report submitted pursuant to Part II (12VAC5-219-40 et seq.) of this chapter; and
4. The calendar day immediately succeeding the deadline of a corrective action plan for a reporting entity that fails to comply with its corrective action plan approved pursuant to 12VAC5-219-100.

D. Civil penalties are due 15 calendar days after the date of receipt of the notice of civil penalty imposition or 31 calendar days after the service of a case decision after an informal fact finding proceeding, whichever is later.

E. A reporting entity shall remit a check or money order for a civil penalty payable to the Treasurer of Virginia.

1. If a check, money draft, or similar instrument for payment of a civil penalty is not honored by the bank or financial institution named, the reporting entity shall remit funds sufficient to cover the original civil penalty amount, plus a $50 dishonored payment fee.
2. Unless otherwise provided, the commissioner may not refund civil penalties or fees.

F. A civil penalty imposed pursuant to subsection B of this section is a debt to the Commonwealth and may be sued for and recovered in the name of the Commonwealth.
   1. On all past due civil penalties,the department shall assess and charge:
      a. Interest at the judgment rate as provided in § 6.2-302 of the Code of Virginia on the unpaid balance unless a higher interest rate is authorized by contract with the debtor or provided otherwise by statute, which shall accrue on the 60th day after the date of the initial written demand for payment;
      b. An additional amount that approximates the administrative costs arising under § 2.2-4806 of the Code of Virginia; and
      c. Late penalty fees of 10% of the past due civil penalties.
   2. The department may refer a past due civil penalty for collection by the Division of Debt Collection of the Office of the Attorney General.

Statutory Authority

§§ 2.2-4805, 32.1-12 and 32.1-23.3 of the Code of Virginia.

12VAC5-219-130. Informal fact finding proceeding

A. A reporting entity may dispute the imposition of a civil penalty pursuant to subdivision B 2 of 12VAC5-219-110 by requesting an informal fact finding proceeding:
   1. In writing to the commissioner; and
   2. No more than 14 calendar days after the date of receipt of the notice of civil penalty imposition.

B. In requesting an informal fact finding proceeding pursuant to subsection A of this section, a reporting entity:
   1. Shall identify with specificity the reason or alleged good cause for its failure to report; and
   2. May present factual data, argument, information, or proof in support of its reason or alleged good cause for its failure to report.

C. The request for an informal fact finding proceeding:
   1. May not toll the imposition of a civil penalty on a per day basis, as specified in subsection B of 12VAC5-219-120;
   2. Shall toll all assessments and charges under subdivision E 1 of 12VAC5-219-120 until a case decision after an informal fact finding proceeding has been served.

D. If a reporting entity does not request an informal fact finding proceeding pursuant to subsection A of this section, the civil penalty imposed pursuant to subdivision B 2 of 12VAC5-219-110 shall be final on the 15th calendar day after the date of receipt of the notice of civil penalty imposition.

Statutory Authority

§§ 32.1-12 and 32.1-23.3 of the Code of Virginia.

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Statutory Authority

§ 32.1-23.3. Prescription drug price transparency; civil penalty.

A. As used in this section, "nonprofit data services organization" means the nonprofit organization with which the Commissioner has negotiated and entered into a contract or agreement for the compilation, storage, analysis, and evaluation of data submitted by health care providers pursuant to § 32.1-276.4.

B. The Department shall negotiate and enter into a contract or agreement with a nonprofit data services organization to annually collect, compile, and make available on its website publicly available information about prescription drug prices submitted by health carriers and pharmacy benefits managers pursuant to § 38.2-3407.15:6, wholesale distributors pursuant to § 54.1-3436.1, and manufacturers pursuant to § 54.1-3442.02. Such data and information shall be made available in aggregate in a form and manner that does not disclose or tend to disclose proprietary or confidential information of any health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer.

C. A health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer that fails to report information required to be reported pursuant to this section or § 38.2-3407.15:6, 54.1-3436.1, or 54.1-3442.02, respectively, shall be subject to a civil penalty not to exceed $2,500 per day from the date on which such reporting is required, to be collected by the Commissioner and deposited into the Literary Fund. However, the Commissioner may reduce or waive a civil penalty imposed pursuant to this section if he determines that the violation was reasonable or resulting from good cause.

D. The Department shall adopt regulations to implement the provisions of this section, which shall include (i) provisions related to the specification of prescription drugs for the purpose of data collection and procedures for auditing information provided by health carriers, pharmacy benefits managers, wholesale distributors, and manufacturers and (ii) a schedule of civil penalties for failure to report information required pursuant to this section or § 38.2-3407.15:6, 54.1-3436.1, or 54.1-3442.02, which shall be based on the level of severity of the violation.

E. All information submitted by a health carrier or pharmacy benefits manager pursuant to § 38.2-3407.15:6, a wholesale distributor pursuant to § 54.1-3436.1, or a manufacturer pursuant to § 54.1-3442.02 shall be confidential and exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq.), except to the extent that such information is included in an aggregated form in the report required pursuant to this section.

§ 32.1-12. Regulations, variances and exemptions.