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

A full recording of the meeting can be found here.

Stakeholders and Attendees Present: Deborah Waite; Kyle Russell; Michael Trent Lundberg; Alex Thorup; Andreew O'Connor; Andrew Lamar; Ann Harbour; Anne Leigh Kerr; Bea Gonzalez; Becky Bowers-Lanier; Ben Barber; Beth Medina; Bradley Marsh; Christina Barrille; Chuck DuVall; Crystal May; Del. Mark Sickles; Deron Johnson; Don Harris; Doug Gray; Edward McAdam; Howard Estes; Hunter Jamerson; Jennifer Reck; Jennifer Sayegh; Jevonte Blount; Jill Hankin; Johanna Butler; John Efinger; Joseph Kupiec; Josh Humphries; Judith Mehm; Julie Fairbanks; Karin Addison; Kelsey Wilkinson; Kirby Consier; Kristin Parde; Laura Lee Viergever; Lauren Rowley; Lu Anne Bankert; Lucy Ackerly; Mark Hickman; Michelle Satterlund; Natalie Snider; Nicole Lawter; Paul Speidell; Rachel Dyer; Richard Grossman; Ryan O'Toole; Scott Castro; Scott Johnson; Stephen Hogge; Terri Dickson; Tim Litten; Tripp Perrin; Tyler Cox; Valentina Vega; Will Dane.

VDH Staff Present: Brenden Rivenbark; Joe Hilbert; Melissa Moore; Mike Sarkissian; Mylam Ly; Rebekah Allen.

Other Staff: Alllyson Tysinger, Senior Assistant Attorney General/Chief.

Call to Order
Mr. Hilbert called the meeting to order at 1:33pm.

Welcome and Introductions
Mr. Hilbert welcomed those in attendance to the meeting. Mr. Hilbert then started the introductions of the stakeholders present and VDH staff present. Mr. Hilbert reviewed the agenda.

Initial stakeholder feedback
Mr. Johnson discussed the definition of price throughout the document and asked for clarification on several areas in the proposed regulation.

Ms. Vega stated the Medical Society of Virginia is supportive of this work and looks forward to providing feedback and additional discussions.

Ms.Kerr stated that her team was working to compare language to that of other states and will be providing written comments by 5:00 PM on Tuesday, May 18th.

Mr. Gray stated VAHP recently submitted a request for technical amendments to draft regulatory text, mainy to more clearly apply definitions.

Ms. Rowley discussed her comments mirror that of Mr.Gray's and written comment will be provided by close of business Tuesday.

Public Comment Period

Dr. Harry Gewanter discussed several items in the regulations. Further details can be found in the written comments at the end of this document.

Ms. Ann Harbour echoed Mr. Gray's comments from the beginning of the meeting and provided written comments.

Mr. Deron Johnson concurred with comments made by VaBio at the beginning of the meeting and provided written comments through association partners.

Section by Section Review of Draft Regulations

12VAC5-219-10 Definitions

No comments were provided on this section.

12VAC5-219-20 Registration

There was discussion on duplicative reporting.

12VAC5-219-30 Notice

No comments were provided on this section.

12VAC5-219-40 Carrier reporting and contract requirements

There was discussion on supporting information for validation, clarification on reporting requirements by groups or individual dosage and/or formulation, and suggested terms.

12VAC5-219-50 Pharmacy benefits managers reporting requirements

Ms. Rowley and Ms. Snider would provide written suggestions for revisions. There was discussion on rebates.

12VAC5-219-60 Manufacturer reporting requirements

There was discussion in subsection B(8) on the submission of "additional information" and clarification on various data components such as Wholesale Acquisition Cost (WAC).

12VAC5-219-70 Wholesale drug distributors reporting requirements

A suggestion was made to change "distribute" to "dispensed" in section B and C.

12VAC5-219-80 Method of report submission

No comments were provided on this section.

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

There was discussion on the difference between "data validation" and "data auditing," and if "after submission" should change to "after receipt."

12VAC5-219-100 Audit; corrective action plan
No comments were provided on this section.

12VAC5-219-110 Disciplinary action
There was a discussion on criminal penalties.

12VAC5-219-120 Civil penalty
There was a discussion on penalties going to the literary fund, and timeframes for section B. Mr. Hilbert provided an overview of the graduated penalty structure.

12VAC5-219-130 Informal fact finding proceeding
No comments were provided on this section.

Next Steps
Written comments are due close of business on Tuesday May 18 to Joe Hilbert.

Adjourn
Meeting adjourned at 2:33pm.

Feedback submitted are on the following pages.

AARP Virginia

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Virginia Department of Health
Attn: Joseph Hilbert
PO Box 2448
Richmond, VA 23218-2448

Dear Mr. Hilbert,

Thank you for the opportunity to submit comments regarding 12VAC5-219 Prescription Drug Price Transparency Regulation. Please let me know if you have any questions regarding the following comments.

12VAC5-219-10. Definitions

"Therapeutically equivalent" – Propose restructuring this definition. The way it is written, for a drug to be "therapeutically equivalent", it would need to be both a drug and a biosimilar.

Suggested edit:

"Therapeutically equivalent" means a drug that:

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

12VAC5-219-20. Registration

A. 3. "electronic address" – Should specify whether this is an email address or an URL.

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

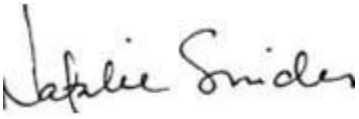
B. 1. “supporting information for validation” – is this a known set of information? If not, it should be spelled out.
C. 1. “all drug products of an outpatient prescription drug” – is this grouping all dosages and formulations of a product together? For example, would the report say “Prozac” rather than “Prozac 100 mg capsule”? Statistically it would make a difference if a carrier is counting all instances of Prozac or all instances of Prozac 100 mg capsules.
D. “The carrier shall report…” – Could this be simplified to say “The carrier shall report for covered outpatient prescription drugs”? Limiting the report to a smaller subset will provide limited information.
E.
F. .
G. “February 15” – Why does the carrier provide information to the PBM before providing it to the NDSO?

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

A. Suggested rewording: “A reporting entity shall **either** include a signed, written certification of the accuracy of any notification or report to the NDSO **or electronic certification** of their notification or report through the NDSO’s online collection tool.
B. .
C. 1. “Consider recommendations from the reporting entity…” – is this a best practice?

12VAC5-219-120. Civil penalty – The statute says penalties will be deposited into the state Literary Fund, but these regulations do not reference that.

Respectfully submitted,



Natalie Snider
Associate State Director – Advocacy & Outreach
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May 17, 2021

The Honorable M. Norman Oliver, MD, MA
Commissioner
Virginia Department of Health
109 Governor Street
Richmond, VA 23219

Attention: Joseph Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs

Dear Commissioner Oliver:

The Association for Accessible Medicines (AAM) is the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Its core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. AAM members provide more than 36,000 jobs at nearly 150 facilities and manufacture more than 61 billion doses of prescription medicines in the U.S. every year.

We appreciate the opportunity to provide the following comments on the Prescription Drug Price Transparency draft regulations (12VAC5-219):

Proposed Definitions of "Course of Treatment," "30-Day Supply," "Reporting Entity," and "Specialty" and "Therapeutically Equivalent" Drugs

The proposed regulations at 12VAC5-219-10 should be updated to reflect a standard definition of "Course of Treatment" and "30-day Supply." We suggest that the Department instead use a singular concept of "30-day equivalent supply" to replace both proposed definitions. This term is codified in federal regulations by the Centers for Medicare and Medicaid Services (CMS) for the Medicare Part D prescription drug benefit.[1] The Department could modify the proposed definition of "30-Day Supply" to "30-Day Equivalent Supply," and delete the term "Course of Treatment" as it would no longer be needed.

We suggest the following definition of "30-Day Equivalent Supply":

> "30-Day Equivalent Supply" means the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days or less. 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 Equivalent Supply.

[1] 42 CFR § 423.104(d)(2)(iv)(A)(2)

The proposed definition of "Specialty" drugs includes the following: "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." Again, we recommend that the definition be modified to link the term "costly" to the specialty tier cost threshold established by CMS and used in the Medicare Part D prescription drug benefit.[2] This threshold, which is reviewed annually, is currently set at $780 for a 30-day equivalent supply. Using this metric instead of a more ambiguous "costly" will provide specificity for reporting entities and the Commonwealth when preparing their annual reports and will ensure the integrity of the results, as each manufacturer will be using the same definition.

Similarly, we recommend that the proposed definition of "Therapeutically Equivalent" be replaced with a reference to the definition of the term as established by the U.S. Food and Drug Administration (FDA). This will reduce any discrepancies between the two definitions, reducing uncertainty for reporting entities and the Commonwealth.

Finally, the definition of "Reporting Entity" should be clarified that a family of affiliated companies, wholly owned by the same ultimate parent, need only maintain one registration with the Commonwealth.

Needed Clarifications for Reporting Requirements and Timeframes from Statutory Text

The section on Manufacturer Reporting Requirements (12VAC5-219-60) contains requirements and reporting timeframes that require clarification. While we recognize that these ambiguities are included in the statutory text, they complicate efforts to implement and follow the law in good faith. Therefore, we recommend that the Department use their authorities under §32.1-12 of the Code of Virginia to clarify these sections through the final regulations implementing the law.

Section A(2) of the legislation does not specify a reporting period for impacted biosimilar manufacturers. Section A(1) clearly refers to price increases that take place "over the preceding calendar year." Section A(3) clearly refers to a price increase that results in an increase in the wholesale acquisition cost (WAC) equal to 200% or more "during the preceding 12-month period." However, there is no clear reporting period for the biosimilar launches included in Section A(2). We suggest that the Department clarify that the reporting period is the calendar year preceding the reporting date (e.g., January 1, 2021 – December 31, 2021 for reports due April 1, 2022). This aligns with the requirement for brand-name manufacturers in Section A(1) and provides adequate time for biosimilar manufacturers to determine whether reporting is necessary and to gather and submit all of the relevant data required under the law.

Additionally, the Department should clarify that a biosimilar manufacturer only needs to submit the required data once per biosimilar launch, during the appropriate reporting period. Because a biosimilar

[2] 42 CFR § 423.104(d)(2)(iv)(A)

only launches once, there is a singular "initial WAC" that will not change as the drug remains on the market. A manufacturer reporting under this requirement should not have to continue to report the same data each year thereafter in perpetuity. The language that triggers a report for brand-name drugs and biologics and generic drugs clearly uses "the preceding calendar year" and "preceding 12-month period," respectively. However, there is no such clarity surrounding the requirement for newly launched biosimilars, even though it appears that the legislative intent is to capture the reporting data only during the reporting period in which the biosimilar is launched.

Likewise, we recommend additional clarification regarding the timeline for reporting for generic drug price increases. The statutory language is clear that the triggering event is a 200% or greater increase in WAC over the preceding 12-month period for a generic drug with a WAC greater than or equal to $100 (i.e., the 200% increase threshold applies to the WAC for the drug over the 12 months prior to the price increase). However, the reporting period of this requirement is unclear. For example, if a generic manufacturer institutes a triggering price increase on March 31 of a given year it is not clear whether the manufacturer would be required to include that price increase in a report due on April 1 of the same year (approximately one day after the price increase takes effect). We encourage the Department to clarify that reports should apply to increases taken in the "preceding calendar year", consistent with the requirement applying to brand-name drugs. This clarification would not only standardize reporting obligations for manufacturers who produce both brand and generic drugs, but would also serve the Commonwealth's policy interests by providing a consistent view of price increases over time.

Finally, the use of "average WAC" in the triggering language for reporting in section A(3)(a) of 12VAC5-219-60 needs clarification. Manufacturers need to use the same methodology to calculate the average WAC. This requires both a standard timeframe (e.g., over the preceding 12 months) and a standard methodology (e.g., volume-weighted by sales). Because there is no proposed definition included in the regulations, reporting entities may calculate average WAC using different methodologies, leading to inconsistent data results.

Options for Reporting Entity Answers for Required Data Elements

The final regulations should make sure that acceptable options for answering some of the required data elements are calibrated so that they apply clearly to all reporting entities. For example, multiple data elements are not applicable to a generic drug and it is unclear how a biosimilar manufacturer would respond to one data element. Specifically, we recommend the following clarifications and options:

Data Element Name (Proposed)	Data Element Definition (Proposed)	Recommended Change
Brand-Name Drug or Generic Drug	Whether the drug is brand-name or generic	Change Data Element Name to include biosimilars and biologics, and include all four categories in the Data Element Definition

Subject to Generic Competition	Whether the drug is subject to generic competition as of December 31 of the preceding calendar year	"Not applicable" or "N/A" should be a reporting option for biosimilar manufacturers reporting on a biosimilar launch price, since the traditional concept of "generic" does not apply to biologics or biosimilars. Generic manufacturers reporting due to a change in WAC should also have the option to answer "not applicable" or "N/A," as by definition, the drug is subject to generic competition if it is a generic drug.
Date of Initial Generic Competition	The month and year of initial generic competition	"Not applicable" or "N/A" should be a reporting option for biosimilar manufacturers reporting on a biosimilar launch price or a generic manufacturer reporting due to a change in WAC. This requirement appears targeted to brand-name drugs. We encourage the Department to clarify that a generic manufacturer is not required to complete this data field given that the reporting manufacturer may not produce the at-the-time first available generic. For biologics and biosimilars, the traditional concept of "generic" does not apply.
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	This data element is redundant, as it can be inferred from answers to the "Subject to Generic Competition" data element.
Date of Initial Availability of Therapeutically Equivalent Generic Version	The month and year of initial availability of a therapeutically equivalent generic version	This data element is redundant, as it can be inferred from answers to "Date of Initial Generic Competition"

Effective Date of Change in WAC	The month and year that WAC changed	"Not applicable" or "N/A" should be a reporting option for biosimilar manufacturers reporting on a biosimilar launch price, not a change in WAC.
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	"Not applicable" or "N/A" should be a reporting option for biosimilar manufacturers reporting on a biosimilar launch price, not a change in WAC.

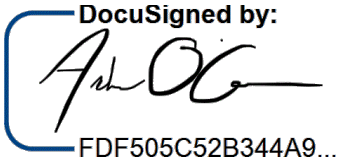
Data Validation, Notification, and Responses

The statutory text authorizes the non-profit data services organization (NDSO) to complete data validation after submission and to notify a reporting entity if the NDSO cannot validate the data submitted by a reporting entity (12VAC5-219-90). While the NDSO is required to notify the reporting entity if a report is found to be deficient, and reported entities are able to submit an updated report in response, we recommend that the regulations require the NDSO to send a second notice to the reporting entity if the NDSO finds that the updated report is still found to be deficient. There can be lots of uncertainty about what exactly needs to be reported and how, especially with new reporting requirements. Therefore, reporting entities should be able to open a dialogue with the NDSO to satisfy deficiencies in a collaborative manner. This is especially important if the reporting entity is still within the 30-calendar day timeframe after the initial notification from the NDSO that the initial report was deficient.

Thank you for the opportunity to provide these comments on the draft regulations. We look forward to working with the Department to ensure that the statute is implemented in a manner that achieves the legislative objectives while reducing burdens on reporting entities.

Sincerely,

DocuSigned by:



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Andrew O'Connor
Senior Manager, State Government Affairs

Comments on 12VAC5-219 Prescription Drug Price Transparency Draft Regulations

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General Comments

I applaud you for trying to make sense of this complex morass of drug prices and costs. My general comments and concerns will reappear throughout the specific comments and questions below as I consider these issues to be crucial to obtaining valid and usable data for both policymakers and the public.

A major concern lies within the corporate vertical integration of all the players in the drug delivery systems and their interconnected financial arrangements. PBMs and insurers are now single companies (UHC/Optum, Aetna/CVS, CIGNA/ExpresScripts). Many of these companies also own specialty and/or commercial pharmacies. We have evidence from Ohio and other states of companies funneling business to their own outpatient and specialty pharmacies and paying independent pharmacies less than their "in-house" pharmacies. How to tease out these financial and other relationships and include their impact on drug prices and costs to the system as well as the individual consumer will be difficult, to say the least, but necessary to obtain as much transparency as possible. Without being able to more specifically clarify "where the money goes" could make all of the collected information less than useful.

Who is the "customer" is a basic question, but one that must be clarified within the regulations. Is it the patient who is using the medication? Is it the company who has a contract with the health plan? Is it the health plan who has a contract with the PBM? Is it the pharmacy who has a contract with the PBM and wholesaler? How to create regulations that tease out all of these and other relationships to illuminate the reality of drug prices and costs is important.

There are now "curative" biologic medications/treatments for genetic and other disorders that have a high initial price/cost but have long-term value in total medication savings. How will these medications be addressed within these regulations?

Finally, and this will reappear throughout my more specific comments, is the need to clarify the differences between prices and costs. There are many prices listed and reported by everyone within the drug supply chain, but the listed prices are not

reality. Given all the price concessions and other contractual arrangements within the system, the "final price" is not known. A better way to consider this issue is to look at "gross prices" and "net costs", better elucidated by Adam Fein. Until all of the price concessions (i.e., rebates, fees, discounts, formulary placement charges, etc.) are identified, the true "drug price" is not known. I also consider it important to clarify the prices and costs at each step within the drug supply chain so that we can have adequate transparency for the consumer to explain their actual cost after accounting for their premiums, copays, coinsurance and out-of-pocket payments.

Section 10 - Definitions

Biosimilar - Why use the Code of Virginia definition for this when you use the FDA definition for "Biologic"? Why not use the FDA definition for both since that is the entity that approves them?

Cost - Who are you referencing when you state "expense incurred"? Is it the enrollee, PBM, health benefit plan and/or some other entity? Are you differentiating between the net or gross cost? How are you differentiating this from "Price"?

Course of treatment - This is very vague and seems to be better suited for acute situations rather than chronic problems. How will this be applied to an illness that may require months or years of treatment? How will this apply to lifetime therapies such as the recently approved genetic therapies?

Discount - There are many opportunities for each entity to create its own definition(s) of what constitutes a discount - or is not a discount. For example, is a fee considered a discount? How about a rebate? Are copays or coinsurance considered a discount? It may be more inclusive to consider using terms such as "total price concessions" for the "discounts" negotiated/obtained by PBMs, insurers or wholesalers and separate those "discounts" from those at the point-of-sale or copay assistance. The sources and intents of these "discounts" are different and should not be lumped into one category to achieve greater transparency.

Enrollee - Is the enrollee the person entitled to care or the contracting entity? PBMs have consistently stated that their customer - AKA enrollee - is the health benefit plan, company or other entity with whom they contract and not the individual patient. It may be beneficial to consider separating out the contracting entity and the patients in your definitions and data as that would provide increased transparency.

Outpatient prescription drug - Are mail-order and/or specialty pharmacies considered to be an "outpatient pharmacy"? Since you are excluding "physician-administered drugs", I think you should be more explicit elsewhere within the document since these types of infusion drugs are among the most expensive medications used. Similarly, there are stand-alone infusion centers; would they be considered within this category?

Price - There are so many "prices" within the system that this definition the is an inadequate and unhelpful definition. There either requires additional explanation and/or be divided into multiple definitions to obtain accurate data. Renaming this the "Patient out-of-pocket cost" would better fit the definition as written.

Among the various "prices" within the system are at least the manufacturer's list prices, the prices listed by PBMs to their customers, the actual price the PBMs, insurers and wholesalers pay to the manufacturers, the prices pharmacies pay to the PBMs and wholesalers, the prices the PBMs list as what they will pay the pharmacies, the prices the pharmacies list for the customer, etc.

In addition, there are what Adam Fein calls the gross price/cost (AKA the "list drug price") and the net price/cost (AKA the actual price for the PBM) and those numbers are completely different by many, many dollars. The discrepancies between the listed prices and the actual costs to the insurers, PBMs, wholesalers, pharmacies and consumer need to be better teased out within these regulations if policymakers and the public will have any hope of using this data to understand drug prices and costs.

Rebate - This may be my problem, but I could not find § 38.2-3407.22 in the online Code of Virginia. Will "rebate" be defined as in the statute as "all price concessions" or as the stricter definition of the contractually defined discounts that are, for example, listed within Medicare and/or Medicaid? PBMs and others have required additional price concessions as fees, discounts and other terms to obtain additional monies from manufacturers without having to reveal all these monies as rebates to their customers.

Creating a definition of "All price concessions" and then having all the various concessions listed would go a long way towards increasing drug price transparency.

Specialty drug - This definition is incomprehensible as written, and I am concerned that this will allow significant room for interpretation and inadequate, incomprehensible and incomparable data.

Section 40 - Carrier reporting and contract requirements

Part B - Are the drugs to be reported by price/cost to be determined by the gross or net prices/costs? Is this before or after all price concessions or both? Why not also have the greatest decreases in prices/costs also reported?

Part C - Again, are the reportable drugs to be determined by price, cost and will these be gross or net? Will the reporting include all the price concessions? Will the price concessions include the patient's payments, use of coupons, etc?

Part D - How will the premium reductions be calculated? What data will be used to perform these calculations and will it be listed in the reports so actual comparisons can be made.

Given the difficulties listed in the definition of specialty drug listed above, the data obtained in this part may or may not be useful.

Parts F & G - Since many, if not most PBMs are now an integrated part of insurers (AKA the same company), how will this data be isolated and reported? I am concerned that various internal business accounting activities could be used to present information that may be technically accurate and verifiable, but not actually valid.

Part H — Data Elements - You include brand-name and generic drugs, but not originator biologics or biosimilars; is there a reason or is this an oversight?

Why not also ask for the net spending increase referring to list/gross prices/spending so that it can be compared with the net prices/spending after all price concessions?

Why not ask for spending and/or premium decreases referable to prescription drugs?

Section 50 - Pharmacy benefit managers reporting requirements

Part A - Why is only the "rebate" data requested rather than all price concessions. If the "rebate" definition is actually "all price concessions", then I think it would be useful to have the various categories of price concessions detailed to help us learn more about where the money goes.

Part B - To build on the comment above, I think you should add data elements for the various price concession categories beyond the common definition of "rebate".

I realize that the PCMA objected to your ability to learn about Medicare and Medicaid rebates. I thought HB 2007 specifically excluded Medicaid information from your data collection; am I correct? Regardless, I don't understand their objection since the Commonwealth has a vested and significant financial interest in how the citizens' money is spent.

I think there needs to be clarification within the definitions and/or within the data elements regarding who is the "enrollee" of the health (benefit) plans receiving the "rebates". Is it the patient/consumer or the entity contracting with the PBMs?

Section 60 - Manufacturer reporting requirements

Part B - #4 - Are the research and development costs for all medications or specifically for the medications being reported by the carriers and PBMs?

Part C - I do not see any data elements for originator biologic or biosimilar medications.

It would be useful to learn what the total price concessions each manufacturer provides to each carrier and/or PBM (ensuring, of course, the data is anonymized).

There are reports of manufacturers actually losing money to maintain formulary status with specific PBMs. It would be illuminating to have the manufacturers report whether this was true or not within Virginia, and, if so, for how many medications.

Section 70 - Wholesale drug distributors reporting requirements

Part A - Why will this reporting be "optional"? Wholesale drug distributors are critical components within the drug supply system and negotiate contracts with manufacturers and pharmacies that affect the final price paid by Virginians for their medications. Wholesale drug distributors are known to vary which generic medications they provide to pharmacies based upon the price concessions they can obtain from manufacturers, etc., and I would consider it imperative that their data be included within any reports on drug pricing.

Part B - The information listed within this section part is clearer than that listed in any of the other sections, and I think you should consider replicating it throughout the regulations. Specifically, numbers 3 & 4 are sufficiently specific and would better clarify the information obtained by the carriers and PBMs as compared to the use of the term "rebate" in the other sections.

Part D - The data elements "Total manufacturer rebates, discounts and price concessions" as well as "Total pharmacy discounts, dispensing fees and other fees" are excellent and should be used in Sections 40 and 50.

Healthcare Distribution Alliance

PATIENTS MOVE US.

May 18, 2021

Joseph Hilbert
Deputy Commissioner for Governmental and Regulatory Affairs
Virginia Department of Health

Re: Prescription Drug Price Reporting Draft

Commissioner Hilbert:

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing pharmaceutical wholesale distributors, I want to thank you for the opportunity to participate in this process as we work collectively toward the best reporting process for the Commonwealth of Virginia.

First, I am seeking clarity on a few points after reviewing the draft, which I will note below

1. Specific to wholesale distributors, how will they be expected to notify the Department of Health and the NDSO; will VDH use existing license information to make initial contact, or will this be published in the Virginia Register?
2. Wholesale distributors have very specific reporting obligations in-statute:
    - The wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the last calendar year, related to the 25 costliest drugs dispensed in the Commonwealth;
    - The wholesale acquisition cost that the wholesale distributor has negotiated directly with the manufacturer in the current calendar year for the 25 costliest drugs dispensed in the Commonwealth;
    - Aggregate total rebates, discounts, and price concessions negotiated directly with the manufacturer for the 25 costliest drugs dispensed in the Commonwealth in the last calendar year, for business in the Commonwealth, in total; and
    - Aggregate total discounts, dispensing fees, and other fees negotiated in the last calendar year with pharmacies, for the 25 costliest drugs dispensed in the Commonwealth, in total.

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.~~
Aggregate Total manufacturer rebates, discounts, and price concessions	Aggregate total rebates, discounts, and price concessions for each drug directly negotiated with a manufacturer in the last calendar year, for business in the Commonwealth.
Aggregate Total pharmacy discounts, dispensing fees, and other fees	Aggregate total discounts, dispensing fees, and other fees for each drug negotiated in the last calendar year with a pharmacy.

Regarding the language in blue, will this be pre-populated? It appears that it would likely be as the entity is requesting information, but I am unclear.

As to the striken language above, we ask that it be removed as it is not included in the reporting requirements in statute. First, there is an error in the description – wholesalers are to report the current year WAC and previous calendar year WAC, not the two years prior. Second, the manufacturer does not negotiate a minimum and maximum WAC with wholesalers, nor does the statute call for this information. Finally, the report should be clear that the manufacturer and pharmacy rebates, discounts, etc… are in the aggregate per the statute.

Again, thank you for taking the time to review our changes as we navigate the rulemaking process. Please do not hesitate to reach out if you have any questions or comments at wdane@hda.org or (571) 287-3020.

Sincerely,

//wd//

William Dane
Director, State Government Affairs
Healthcare Distribution Alliance

May 18, 2021

Deputy Commissioner Joe Hilbert
Virginia Department of Health
109 Governor Street
P.O. Box 2448
Richmond, VA 23219

VIA Email

Re: Draft Prescription Drug Transparency Reporting Regulation

Dear Mr. Hilbert:

Thank you for the opportunity to provide more specific written comments on the draft Prescription Drug Transparency Reporting Regulation in addition to the verbal comments I provided on behalf of the Pharmaceutical Care Management Association (PCMA) at the Friday, May 14 hearing.

PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

Definitions

"Cost" – the word "cost" is used through the regulation in ways that are inconsistent with the definition in the draft regulation. **We suggest removing the definition.**

"Discount" – the last part of the definition that says, "including point-of-purchase or point-of-sale consumer coupons and copay assistance" is not information a PBM would have access to or knowledge of. When coupons are used by consumers at the pharmacy, the PBM does not know the value and therefore cannot report them. We suggest deleting "including point-of-purchase or point-of-sale consumer coupons and copay assistance" from the definition.

"Price" – the word "price" is used inconsistently to the definition in the draft regulation. **We suggest removing the definition.**

"Specialty Drug" **we recommend that this definition be amended to read**: "Specialty Drug" is a prescription drug that typically is high cost and that: is prescribed for a person with a (a) chronic, complex, or life-threatening condition, and/or (b) rare medical condition; has limited or exclusive distribution; or requires (a) specialized product handling and/or administration by the dispensing pharmacy, or (b) specialized clinical care, including frequent adjustments, intensive clinical monitoring, or expanded services for patients, including intensive patient counseling, education, or ongoing clinical support beyond traditional dispensing activities, such as individualized disease and therapy management to support improved health outcomes.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

1**2VAC5-219-50. Pharmacy Benefits Mangers 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 subsection 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:*

We have significant concern with the italicized language and require clarity from the department on what will be required for reporting purposes.

The statute states that:

> D. Every carrier offering a health benefit plan shall require each pharmacy benefits manager with which it enters into a contract for pharmacy benefits management to report annually by April 1 to NDSO with which the Department has entered into a contract or agreement… the following information for each drug specified by the Department of Health…"

The law goes on to stipulate:

> E. A report submitted by a pharmacy benefits manager pursuant to subsection D shall not disclose the identity of a specific health benefit plan or covered person, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drug.

The statute requires a PBM to report by each drug, but then contradicts itself to say a PBM is not required to submit a report for each drug or would be violating the statutory requirements for the report.

In order not to violate the confidentiality clause that prohibits drug and carrier specific information from being reported, we ask that you consider a similar reporting structure required in Texas that does not identify carriers or drugs. (The Texas reporting form is attached with this letter.)

Data Elements Required

We request the Data Elements listed below in paratheses be deleted from the required reports:

> "Medicaid rebates, before federal and state rebates"
> "Medicaid rebates passed on, before federal and state rebates"

These data element requirements are beyond the scope of the statute and would violate the requirement that a PBM not disclose the identity of a specific plan as many PBMs only have one plan in this category. Additionally, PBMs do not have all of the information these data elements require and therefore could not comply with the reporting requirement.

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"Medicare rebates"
"Medicare rebates passed on"

These data element requirements go beyond the scope of the statute and the state does not have the authority to require this information. State laws that operate "with respect to" a Medicare standard are preempted by federal law. This preemption is long-standing and was not changed in the recent Supreme Court decision in *Rutledge v. PCMA.*

"Other payer rebates"
"Other payer rebates passed on"

The Department does not have the authority to collect this information. In 2016, the Supreme Court ruled, in *Gobeille v. Liberty Mutual Insurance Co., Inc.*, that state-mandated reporting of health claims data from self-insured health plans to Vermont's APCD was preempted by the federal Employee Retirement Income Security Act (ERISA). The six-to-two opinion was written by Justice Anthony Kennedy, with Justices Ginsburg and Sotomayor in dissent. ERISA contains a broad preemption clause, which establishes that ERISA supersedes any and all state laws insofar as they relate to any employee benefit plan.

In *Gobeille*, the Court ruled that, because "[d]iffering, or even parallel, regulations from multiple jurisdictions could create wasteful administrative costs," the statute (establishing Vermont's APCD) is preempted.

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

We request clarification on what the difference is between "data validation" and "audits", as both are required in this rule.

12VAC5-210-110.Disciplinary action

This section allows the commissioner to "refer the reporting entity for criminal prosecution." The statute authorizes the department to levy civil penalties, not criminal penalties, so we request this be deleted from the rule.

Thank you for your consideration of our comments. I am happy to answer any questions you may have and may be reached at lrowley@pcmanet.org or by phone at 703-300-3507.

Sincerely,

Lauren Rowley

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Washington, DC 20004
www.pcmanet.org

Texas Department of Insurance

PO Box 149104 | Austin, TX 78714 | 1-800-578-4677 | tdi.texas.gov

Pharmacy benefit manager reporting form

Under Texas Insurance Code Section 1369.502, the report is due by **February 1 of each year**.

More information about this report is located on the pharmaceutical benefits reporting index page.

Company information

Company name: _____
NAIC number (if applicable): _____
TDI number: _____
Submission date: _____
Reporting Year: _____

Address: _____
City: _____
State: _____
ZIP: _____

Contact information

Contact name: _____
Title: _____
Phone number: _____
Email address: _____

Address: _____
City: _____
State: _____
ZIP: _____

May TDI release this email address? _____

☐ This company is not a pharmacy benefit manager.

All pharmacy benefit managers fill in the information below.

Aggregate rebates, fees, price protection payments, and other payments

Amount passed to issuers: _____

Amount passed to enrollees: _____

Amount retained as revenue: _____

Total amount collected from pharmaceutical drug manufacturers: _____

Print form Submit by email

PhRMA
RESEARCH • PROGRESS • HOPE

950 F STREET NW, SUITE 300, WASHINGTON, DC 20004 | 202.835.3552 | PhRMA.ORG

May 18, 2021

Joseph Hilbert
Deputy Commissioner for Governmental and Regulatory Affairs
Virginia Department of Health
109 Governor St
Richmond, VA 23219

Submitted via electronic mail: joe.hilbert@vdh.virginia.gov

Re: Chapter 304 of the 2021 Acts of the Assembly, Draft Regulations

Dear Mr. Hilbert:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA respectively submits our concerns related to the draft regulations published by Virginia Department of Health ("the Department") on May 7, 2021 as proposed 12VAC5 chapter 219, implementing the requirements of House Bill 2007, Prescription Drug Price Transparency, which was enacted in the 2021 Legislative Session and printed as Chapter 304 of the Virginia Acts of Assembly ("the Act").

The bulk of our concerns in the draft regulations center around the expansion of the Department's authority, as well as the authority delegated by the Department to the Nonprofit Data Services Organization ("NDSO"), including additional reporting and registration requirements and criminal prosecution referral authority. These requirements are not included in the Act, and PhRMA requests that the Department not include any elements in its final regulations that are not consistent with its authority in the Act.

12VAC5-219-60 Manufacturer Reporting Requirements

PhRMA has significant concerns with several provisions of 12VAC5-219-60 and requests deletion or clarification as appropriate.

Section (B)(8) Reporting of "Supporting Documentation"

PhRMA is concerned about the inclusion of Section (B)(8), which requires manufacturers to provide "Supporting documentation required by the NDSO to validate all information required by this section." Such supporting documentation is not required under the Act, and this provision expands NDSO authority by permitting it to require additional information from manufacturers as it determines necessary. In addition, this provision ignores the guideposts established in the Act that detail what specific information is required from reporting entities. Finally, NSDO requests for this information are an unnecessary expansion of its statutory responsibilities and authority. An audit function is already provided for in the Act (under Va. Code § 32.1-23.3(D)), which the Department has addressed in section 12VAC5-219-100 of its draft regulations. Requiring additional information beyond the scope of what the Act requires and outside of the Act's contemplated audit process is unnecessary, duplicative, and goes beyond the Department's authority as provided in the Act. PhRMA strongly recommends the deletion of Section (B)(8).

Section (A)(1) Reporting Triggers

PhRMA requests that the Department confirm that (A)(1) reflects the statutory language in Section 54.1-3442.02(B), which limits reporting requirements to drugs with both (1) WAC of $100 or more for a 30-day supply or single course of treatment **and** (2) an increase of 15 percent or more in the WAC over the preceding calendar year.

12VAC5-219-60 Manufacturer Reporting Requirements: Data Element Chart

PhRMA is concerned that certain data elements included in the Data Element Chart at 12VAC5-919-60(C) are items that manufacturers are not required to report under the Act, and that inclusion of these items in the draft regulations therefore exceeds the scope of the Department's authority. PhRMA also has specific objections to certain of these items as described below. PhRMA requests that these data elements not be included in the final regulations:

- WAC Unit
- Medi-Span© Generic Product Identifier (GPI): Medi-Span© GPI is a proprietary data element of Medi-Span's drug pricing compendium, and manufacturers may not have access to this information.
- Date of Initial Generic Competition
- Date of Initial availability of Therapeutically equivalent generic version
- Year of Market Introduction
- WAC at market introduction
- Current year minus one WAC
- Current year minus two WAC

Section D Reporting Requirements

PhRMA requests that the regulations utilize the statutory language which provides clear guidance to reporting entities regarding which materials satisfy a reporting obligation. Va. Code § 54.1-3442.02(C) states that a manufacturer's reporting obligation is fully satisfied by the disclosure of information in "the manufacturer's annual consolidation report the Securities and Exchange Commission Form 10-K or any other public disclosure." However, the implementing regulations do not specify that a manufacturer's obligations will be considered "fully satisfied" as a result. PhRMA requests that the language in 12VAC5-219-60(D) be amended to accurately reflect the statutory language:

> *"A manufacturer's obligations pursuant to the section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to Section 32.1-23.3 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure." Section 54.1-3442.02(C)*

Comments Field

PhRMA requests that the Department consider providing a "Comments" field for reporting, which would allow manufacturers to include in their reports additional information that they may want to provide.

12VAC5-219-110 Disciplinary Action

PhRMA has significant concerns with a provision in the draft regulations that provides for potential referral for criminal prosecution of reporting entities.

The Act, at Va. Code 32.1-23.3(C), delineates the maximum civil penalty for an entity that fails to comply with its reporting requirements, and permits the Virginia State Health Commissioner wide latitude in reducing (but not increasing) the civil penalties that it assesses: "A health carrier, pharmacy benefits manager, wholesale distributor, or manufacturer that fails to report information required to be reported ... shall be subject to a **civil penalty** not to exceed $2,500 per day from the date on which such reporting is required ... 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." (emphasis added). The Act instructs the Department to implement rules regarding these penalties, and specifically to establish "a schedule of **civil penalties** for failure to report information required ... which shall be based on the level of severity of the violation." Va. Code 32.1-23.3(D) (emphasis added). There is no reference in the Act to criminal penalties.

Despite the Act's unambiguous specification that violations of its requirements are to be subject to civil penalties, the draft regulations permit the State Health Commissioner to "[r]efer the

reporting entity for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia ..." This exceeds the Department's authority under the Act and provides the Commissioner with additional authority to leverage possible criminal prosecution against alleged violators despite the clear intent of the legislature. PhRMA requests that the provision in 12VAC5-219-110(B)(1)(a), allowing for referrals for possible criminal prosecution of alleged violators, be removed from the final version of the regulations.

12VAC5-219-100 Audit; corrective action plan

PhRMA is concerned with the provision in 12VAC5-219-100(B) that shifts the costs of audits under the Act to the audited reporting entity: "The reporting entity shall be responsible for the cost of any independent external audit initiated pursuant to this section." This mandate is not established in the Act, nor was it considered in the corresponding Department of Planning and Budget 2021 Fiscal Impact Statements. PhRMA is also concerned that there is no opportunity for manufacturers to provide input on the scope of a proposed audit, and that there are no limitations on the scope of the audits to prevent unnecessary or unduly broad audits, the costs of which would be assessed against the reporting entity. Therefore, PhRMA requests that this provision be stricken from the final regulations.

12VAC5-219-10 Definitions

PhRMA seeks clarification and/or removal of several of the terms included in the definitions section of the draft regulations to ensure statutory alignment and resolve ambiguity.

- "Discount" – This definition in the draft regulations extends beyond the traditional scope of the term. The definition of "discount" in the draft regulations states: "'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." The inclusion of point-of-sale consumer coupons and copay assistance is inappropriate in this context as such discounts are solely intended to provide financial benefit directly to a consumer and not to impact payors, pharmacy benefit managers, wholesale distributors, or other supply chain entities. PhRMA recommends that "point-of-sale consumer coupons and copay assistance" be removed from the definition.
- "Launched" – PhRMA recommends that the definition be further clarified to limit "launched" to the date that a product is first made available for sale in Virginia. In addition, we request the removal of the word "acquired" as it is an additional data point not required by the Act and could cause confusion because it incorporates into the definition a concept that is not commonly understood to be a "launch."
- "Price" –PhRMA recommends striking this term from the final regulations. Wholesale Acquisition Cost is the metric used throughout the reporting requirements and is defined in the Act, so the term "price" is could lead to confusion. Furthermore, "price," as defined, is a function of insurance benefit design and is not determined by the manufacturer.
- "Specialty Drug" – The definition of specialty drug in the draft regulations uses ambiguous terms, including whether a drug is "costly," in order to determine whether it is

considered a "Specialty Drug." PhRMA recommends replacing the definition with the following: "'Specialty drug' means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services."

12VAC5-219-20 Registration

PhRMA is concerned that the draft regulations establish a duplicative reporting structure by requiring that reporting entities supply both the Department and the NDSO with registration materials. PhRMA believes this requirement is inconsistent with Section 54.1-3442.02(B) of the Act, which states, "Every manufacturer shall report annually by April 1 to the nonprofit organization with which the Department of Health has entered into a contract or agreement pursuant to Section 32.1-23 ..."

In closing, we would appreciate guidance in the final regulations on the process for dispute resolution throughout the reporting process, including but not limited to challenges to initial findings, request for report corrections, and proposed audits. In addition, we believe it is integral that all reporting entities have an opportunity to submit comments on any additional materials that the department may develop to implement these requirements.

Thank you for the opportunity to engage with the Department on the draft regulations for Chapter 304 of the 2021 Acts of the Assembly. We remain committed to discussing these issues with you and working collaboratively toward their resolution. Please do not hesitate to contact Kristin Parde at kparde@phrma.org to discuss these items further.

Sincerely,

Kristin Parde
Deputy Vice President

FirstChoice
CONSULTING

May 18, 2021

Via Email: joe.hilbert@vdh.virginia.gov
Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs
Department of Health
James Madison Building
109 Governor Street, 13th Floor
Richmond, VA 23219

Re: Stakeholder Comments to 12VAC5-219
Prescription Drug Transparency Regulations

Dear Joe:

I trust this letter finds you doing well. I am writing to you on behalf of the Virginia Biotechnology Association (VaBio). At the outset, we want to convey, again, our gratitude and appreciation for the work of you and your team in taking the initial pass at drafting the regulations and convening the stakeholder meeting Friday, May 14. Pursuant to your request at our stakeholder meeting, VaBio is pleased to submit this correspondence to memorialize the feedback offered during the stakeholder meeting.

The first comment shared on behalf of VaBio is found on page 4 of the draft regulations, located in "12VAC5-219-20. Registration." Specifically, as drafted, this regulation requires a reporting entity to furnish a report to both the Virginia Department of Health (the department) and the nonprofit data services organization (NDSO). We do not think duplicative reporting is intended by the statute or by the department. Accordingly, VaBio recommends the "and" be changed to "or" in both Paragraphs A and B of this regulation, in order to avoid duplicative reporting.

VaBio has heard from members regarding several of the definitions set forth in these regulations and their applicability in the reporting requirements. Specifically, on page 2, the definition of "price" appears to capture a price at "retail." However, the manufacturer reporting requirements set forth in 12VAC5-219-60, located on page 9, the use of "price" creates a reporting conflict. Specifically, manufacturers under this regulation are required to report information on generic drugs with a price increase of a certain amount. The manufacturer's obligation is to report on wholesale prices, not retail prices, so the use of the word "price" as defined, creates a conflict. VaBio recommends you either strike the definition of "price," or in the alternative, exclude manufacturer reporting from the definition of "price."

Next, VaBio heard feedback regarding the definition of "specialty drug" located on page 3. Specifically, the definition starts off with the phrase "means a drug that is costly. . . ." This is a very subjective term and VaBio recommends the definition be revised to delete this.

Next, VaBio commented on the manufacturer reporting requirements as set forth in regulation "12VAC5-219-60. Manufacturer reporting requirements." This regulation is in conflict with both the statute and paragraph D in the regulation. The statute governing manufacturer reporting, 54.1-3442.02, paragraph C, provides that "a manufacturer's obligations pursuant to this section shall be fully satisfied by the submission to the nonprofit data services organization with which the Department of Health has entered into a contract pursuant to § 32.1-23.3 of information and data that a manufacturer includes in the manufacturer's annual consolidation report on Securities and Exchange Commission Form 10-K or any other public disclosure."

Paragraph 8 of 12VAC5-219-60 is in conflict with this statutory section, as it requires a manufacturer to submit "8. Supporting documentation required by the NDSO to validate all information required by this section." Further, paragraph D, located on page 10 of 12VAC5-219-60, correctly tracks the statutory requirements noted above. Thus, the statute and paragraph D are consistent, but paragraph 8 is not. Accordingly, we would request paragraph 8 be deleted in its entirety.

Finally, VaBio commented on the data elements for reporting, located on page 9 in the drafted use of phrases such as "Current year minus one WAC" and "Current year minus two WAC." It was suggested that a better way to phrase this would be "WAC on January 1 of the prior year" and "WAC on December 31 of the prior year."

VaBio stands ready to continue to work with the stakeholders as this process advances and we look forward to seeing the revised draft regulations and participating in the Virginia Department of Health's meeting on September 2, where these regulations will be acted on.

Very truly yours,

W. Scott Johnson

cc: John Newby, CEO/VaBio
Caron Trumbo, VP Operation/VaBio
Tyler S. Cox, Governmental Affairs Manager/FirstChoice Consulting

#1179556

VAHP
VIRGINIA ASSOCIATION OF HEALTH PLANS

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email: info@vahp.org · website: www.vahp.org

Mr. Joe Hilbert
Deputy Commissioner
Virginia Department of Health
109 Governor Street
P.O. Box 2448
Richmond, VA 23219

VIA EMAIL

Mr. Hilbert,

On behalf of the Virginia Association of Health Plans, please see the below comments on the draft Prescription Drug Price Transparency Reporting regulations.

- Page 1, definition of "Cost" - The word "cost" is used throughout the regulation in ways that are not relevant to this definition.
    - Ex. Page 5, Section 12VAC5-219-40, B. 2. – The use of the word "cost" here does not match the definition as set forth on Page 1.

  We suggest removing this definition from the regulation.

- Page 1, definition of "Discount" – The last clause "including point-of-purchase or point-of-sale consumer coupons and copay assistance" is information that we do not have access to. When these types of discounts are used at retail pharmacies, we do not know the value of these discounts and thus cannot report on them. The transaction with a point-of-sale coupon is separate from the pharmacy claim. Moreover, the way the statute uses discount contemplates discounts flowing from the PBM/carrier and not from other coupon sources. **We suggest deleting the last clause "including point-of-purchase or point-of-sale consumer coupons and copay assistance."**

- Page 2, definition of "Health benefits plan" – While this language matches the statute, we do not report on a policy by policy basis and should instead be required to report on benefit plan type by market segment.
    - For example, Page 5, Section 12VAC5-219-40, A. contemplates aggregate rebate reporting and uses the term "health benefit plan". This will pose problems if we have to report on a policy by policy basis, when instead we should be reporting on a benefit plan type by market segment – ex. Aggregate Rebates in Individual market, Aggregate Rebates in Small Group market, Aggregate Rebates in Large Group market.

  We suggest that reporting requirements be clarified to only report on benefit plan by market segment for a consolidated report. PBM's should also report by market segment.

- Page 2, definition of "Price" – If VDH is insistent on keeping this in the regulation, this should be revised to read "Price" means the amount of money a cash paying customer pays at retail for a drug, biologic, or biosimilar in the absence of a discount, rebate, or price concession. This revision is necessary to not confuse the cost associated with a member's cost share. This is also another example of a definition that doesn't work in all places because the regulation's use sometimes seems to point to the carrier's allowed amount, which is why our priority is that it be deleted from the regulation.
    - Ex. Page 6, Section 12VAC5-219-40, E. – The use of the word "price" doesn't match the definition as set forth on Page 2.

  We suggest removing this definition from the regulation.

- Page 3, definition of "Specialty drug" – This definition should acknowledge a **specialty drug list exists at the PBM/carrier level and these entities may define "specialty drug" differently**. For this, there may be variation in reporting amongst different PBMs/plans. If VDH defines specialty drugs, then each plan would have to recode and reprogram their entire drug classification system, which would be an undue burden for the plans.

  Page 7, Section 12VAC5-219-50, A. 2. and A. 3. – The PBM today distributes rebates to the carrier and not to the health benefit plan. If carriers follow the language of the statute, the correct answers for A.2. and A.3. will likely be zero because the PBM is not distributing rebates to the health benefit plan.
  We suggest the language is changed to reflect that the PBM is distributing rebates to the carrier.

- Page 6, Section G – The carrier's obligation to notify the PBM by February 15 annually should be removed. The PBM's should already have the information since they are benefits and claims data. It also accelerates the timeline to have the report completed to February 15, rather than April 1. The additional time to complete the report would be appreciated.

- Generally, the notification windows for responding to requests, non-compliance, etc., are currently 14 days throughout the regulations. We would appreciate a minimum of 30 days to give plans additional time to respond.

We appreciate your attention to these issues.

Best regards,

Doug Gray
Executive Director

Christina Barrille
Executive Director
info@virginiapharmacists.org

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North Chesterfield, VA 23235
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May 18, 2021

Joseph Hilbert, Deputy Commissioner for
Governmental and Regulatory Affairs,
Virginia Department of Health

VIA EMAIL

Re: Comments on Proposed 12 VAC 5-219 Prescription Drug Price Transparency Regulation

Dear Mr. Hilbert:

Thank you for the opportunity to provide comment on the above-referenced proposed regulations. On behalf of the Virginia Pharmacists Association (VPhA), I write to provide specific comments on the proposed regulations. We represent the pharmacists serving on the frontlines to ensure patients access to low-cost medications. We also represent the pharmacy owners that are being driven out of the market by the destructive business practices of pharmacy benefit managers.

Contrary to other stakeholders who provided commented, we think the definition and use of "health plan" is a useful tool. While you might receive data that is at a larger volume and is duplicative, VDH could simply ask the reporting entity or carrier to note this.

We also want to note that Washington State has some drug pricing reporting requirements (Ch. 43.71C) that does a thorough job of addressing the various aspects that go into drug pricing (e.g., manufacturer rebates, PBM transaction fees and spread, etc.). These definitions may be helpful as the regulations are reviewed and crafted.

Below are the specific comments on the proposal, referencing each section:

12VAC5-219.10 Definitions

We think "Discount" should be redefined as "any price concession, including but not limited to rebates, reductions in price, coupons, out-of-pocket or premium assistance having the effect of reducing the cost of a prescription drug, biologic or bio-similar."

We think the first sentence under the definition "Outpatient prescription drug" should be amended to strike "retail or outpatient" and insert after "pharmacy" the words "licensed to dispense prescription in Virginia, including from a retail, outpatient, mail order or other delivery setting." We think the exclusion in the second sentence is overly broad, particularly with the exclusion of outpatient hospital settings.

We think the term "Price" should also reflect clawbacks, audits, fees and other payments or collected amounts from pharmacies reflected on drugs included in the amounts ultimately reported.

12VAC5-219.50 PBM Reporting Requirements

In our view, reporting "Other Payer Rebates" is not violative of the pre-emption provisions under the federal Employee Retirement Income Security Act of 1974 (ERISA), based on the *PCMA v. Rutledge* decision. The Supreme Court made it clear that pricing and rate regulation (and presumably reporting such data) are not preempted under ERISA and states have regulatory authority.

In Subsection A (p.7), the regulation language could be amended so that where a carrier self-manages the pharmacy benefit or owns its PBM directly, that such carriers need to report the data and require any contracted PBM to do the same.

We appreciate the opportunity to comment, and we stand ready to assist with any follow up questions.

Regards,

Christina Barrille