COMMONWEALTH OF VIRGINIA
Department of Health Professions
Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4648 (Tel)**
Henrico, Virginia 23233 **(804) 527-4434(Fax)**

Tentative Agenda of Pharmacy Benefit Manager Workgroup

December 16, 2015

9:00AM

TOPIC	PAGES
Call to Order of Meeting: David E. Brown, D.C., DHP Director	
Approval of Agenda	
Approval of Minutes	1-6
Call for Public Comment	

Discussion Topics:
• Items from Prior Meeting
  o White-bagging and brown-bagging
  o Waste involved in mail order
• Other	

Discussion and Approval of Draft Report	7-14
Adjourn	

Commonwealth of Virginia
Department of Health Professions
Pharmacy Benefit Manager Workgroup

Friday, November 13, 2015
Perimeter Center, 2nd Floor Conference Center, Board Room 4
Henrico, Virginia

******DRAFT***MEETING MINUTES***

Members Present:

David E. Brown, D.C., Director, Department of Health Professions
John Beckner, Senior Director, Strategic Initiatives, National Community Pharmacists Association
Geoffrey S. Ferguson, RPh, Pharmacist Lead, Anthem Blue Cross and Blue Shield
Douglas Gray, Executive Director, Virginia Association of Health Plans
William L. Harp, MD, Executive Director, Virginia Board of Medicine
Diana Jordan, Director, Division of Disease Prevention, Virginia Department of Health
Caroline D. Juran, Executive Director, Virginia Board of Pharmacy
Michael Jurgensen, Senior Vice President, Health Policy & Planning, Medical Society of Virginia
Jessica S. Mazer, Esq., Assistant Vice President, State Affairs, Pharmaceutical Care Management Association
Timothy S. Musselman, Pharm.D., Executive Director, Virginia Pharmacists Association
Donna Proffitt, Pharmacy Manager, Virginia Department of Medical Assistance Services
Ellen B. Shinaberry, RPH PharmD, Member, Virginia Board of Pharmacy
John Sisto, Senior Director of Regulatory Affairs, Express-Scripts
Van Tompkins, Insurance Policy Advisor to the Commissioner, Virginia Bureau of Insurance
Kenneth J. Walker, MD, Member and President, Virginia Board of Medicine
Sara Wilson, Director, Virginia Department of Human Resource Management

Alternates Participating:

Bill Cropper, Virginia Association of Chain Drug Stores
T.C. Jones, IV, Supervisor, COPN, MCHIP & PRA Programs, Office of Licensure and Certification, Virginia Department of Health

Members Absent:

Rusty Maney, President, Virginia Association of Chain Drug Stores
Elaine Yeatts, Senior Policy Analyst, Department of Health Professions

Staff Present:

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

Opening Remarks

Dr. Brown called the meeting to order at 9:10am. He welcomed the Workgroup members and the public and gave a brief overview of the purpose of the meeting. The Workgroup members and staff introduced themselves. Additional handouts were provided to the Workgroup. These include excerpts of Virginia Laws/Regulations Regarding Complaints/Appeals and Other Relevant Information, Letter to the Workgroup from Mr. John Frye, AHIP Issue Brief on Specialty Drugs, IMS Health White Paper: Succeeding in the Rapidly Changing U.S. Specialty Market, and Employee Benefit Research Institute Fast Facts on Health Plan Differences: Fully-Insured vs. Self-Insured (copies may be obtained from the DHP Director's Office).

Approval of Agenda

Dr. Brown asked if there were any comments concerning the agenda. There being none, the agenda was approved.

Approval of Minutes

Ms. Shinaberry made note of a correction to page two of the minutes on page four of the agenda package – in Mr. Lubkowski's remarks, the references to Sentara should be replaced with "his facility" as he was not speaking on Sentara's behalf. A motion was made by Ms. Wilson to approve the minutes with the noted change, seconded by Mr. Beckner, and the minutes were approved unanimously.

Public Comment

Seven individuals addressed the Workgroup: David Creecy – pharmacist/owner, Poquoson Pharmacy; John Lubkowski, Pharmacy Manager, Sentara; Javier Menendez, Pharmacy Director, Virginia Premier; David Balto – antitrust attorney in Washington, DC and represents the Coalition to Protect Patient Choice; John Seymour, pharmacist/owner, Orange Pharmacy and Elkton Family Pharmacy; Matt DiLoreto, Senior Director, State Government Affairs, NCPA; and Otto Wachsmann – pharmacist/owner, Stoney Creek Pharmacy. Workgroup members were given the opportunity to ask questions of the individuals.

Mr. Creecy discussed prior authorization (PA) issues facing his patients. Examples he cited include delays in receiving medications, up to 7-10 days, due to the back and forth between the prescriber, pharmacist and insurance company. He stated generic Lidoderm was not covered for one of his patients. The branded drug was covered, but cost the patient $100 more per box. Another example involved a patient who responded well to the branded drug, patient informed it required PA, and then informed it must be obtained from a specialty pharmacy. Patient did not receive drug for 8 days, and according to Mr. Creecy, patient suffered in the interim. Mr. Creecy would like to know where they are to refer patients for assistance in these matters and who can be mediator. He feels because PBMs are not regulated, there is no place to turn and complain.

Mr. Lubkowski also cited delays of approximately 7 days in treatment of patients due to delays in PA and dealing with specialty pharmacies. He stated there were times when he had the drug in stock, but could not dispense it since the patient was required to obtain the drug from a specialty pharmacy. He also provided an example of when a drug from a specialty pharmacy arrived at his pharmacy without his facility knowing in advance of the shipment.

Mr. Menendez indicated that PA is a good tool for payers for utilization management and discussed that cost of drugs is high and that something needs to be done. He also stated the PA process allows the pharmacist to catch prescribing errors prior to dispensing.

Mr. Balto indicated that Pharmacy Benefit Managers (PBMs) are the least regulated part of the healthcare market and force patients into wasteful mail order process. Pharmacists in rural areas of Virginia are having a hard time staying in business and are willing to dispense below cost to help their patients. He stated what the Workgroup is considering is very basic in oversight. He also briefly discussed ERISA and pointed out that Iowa passed a law that is more comprehensive than what the Workgroup is considering and that the federal judge indicated that the Iowa law does not violate ERISA. He is also providing testimony in the House Judiciary Committee meeting in November.

Mr. Seymour stated that the Workgroup's purpose is to make recommendations regarding the need for additional oversight of PBMs; however, he is not sure there is any oversight. At the last meeting, no one denied that the health of patients is being affected. Also, PA is not a bad thing, but the process needs to be different with consideration given to the patient's needs. When a generic drug is not covered, but a branded drug is, the patient usually pays more for the drug which pushes Medicare Part D recipients into the donut hole faster. With respect to the argument that employers ultimately determine coverage-related issues, he stated he is a small group administrator and has never had a PBM ask his opinions on establishing formularies or mail order pharmacy options.

Mr. DiLoreto stated that there is a national move on this issue and that most states are taking reasonable reforms action. Licensure and registration is not oversight. He indicated that the Board of Pharmacy has a legitimate case to protect the public and cited that the Mississippi state board requires licensure. Oversight should include proper enforcement penalties.

Mr. Wachsmann indicated that four independent pharmacies have closed in the past few years in his area. He addressed PA issues, delays in patients receiving medications, and that some patients have plans that won't allow their prescriptions to be filled in his pharmacy. If his pharmacy were to close, it would be a hardship for patients to receive their medications as the next nearest pharmacy to his is a 40-mile roundtrip. He referenced the National Association of Boards of Pharmacy (NABP) Task Force report which made recommendations for the states to consider in reference to PBMs.

Workgroup Comments

Mr. Beckner stated that PAs are cost-effective and provide appropriate care; however, the process is cumbersome, affects patient care and cuts across all practice settings, not just independent pharmacies.

White-bagging and brown-bagging are a concern for Ms. Shinaberry due to delays in patients receiving medications in a timely manner. Mr. Gray indicated that consistency around "white bagging" and "brown-bagging" is a problem and that the Board of Pharmacy should probably review it.

Questions for the Workgroup

Dr. Brown brought up questions for the Workgroup to consider:

1. When a patient has a concern about how long it is taking to get a medication or why a more expensive drug is being covered when a generic is available, where can the patient go with a complaint?

   Mr. Gray indicated the patient may go to the administrator of the health plan. If it is a fully-insured plan, the patient may go to the managed care ombudsman. He referenced pages 56, 65, and 79 of the Laws/Regulations handout distributed at this meeting.

   Patient education is important. Ms. Tompkins indicated that the Virginia Bureau of Insurance (BOI) will help direct consumers to the best of BOI's ability. The Workgroup further discussed the complaint process, and Mr. Musselman suggested that BOI's phone number be included on insurance cards for the patient to call when there is a problem.

2. Is there any data as to how frequently patients have a delay?

   Ms. Wilson, speaking from a self-insured standpoint, indicated that an internal ombudsman is required by Code, and an annual report is published. Ms. Shinaberry referenced page 7 of the National Scorecard (page 38 in the Agenda Package) which shows that 40% of PA requests are abandoned.

   Mr. Sisto indicated that PA is a problem and suggested that a technical group be created to educate providers on how the process, including electronic prior authorization (ePA), works and to create a consensus on how to streamline the process. The implementation of ePAs requires an increased use of e-prescribing. The idea was discussed by the Workgroup, and it was decided that such a group would be created. Topics for the group to consider include e-prescribing, inter-operability, transparency, and educating the public on the process.

   Ms. Juran questioned whether drug formularies are available on the internet. They are required by Virginia Code to be in electronic format and can be found on the health plan's website. Mr. Gray referenced item 8 on page 21 of the agenda package and recommended that a demonstration on how the process of PA works, including e-prescribing and ePA.

3. Would regulation create problems or would it help?

   Many on the Workgroup, including those representing pharmacists and pharmacies, appeared to agree that oversight would be good in improving patient safety, access to care, and assisting patients in navigating the system. Those Workgroup members representing PBMs and health plans did not feel additional oversight is needed as they are confident the health plans are adequately overseeing the PBMs that are contracted with the plans.

   Terry Talbot of CVS Caremark was asked to address the Workgroup on CVS Caremark's credentialing process. Although unable to specifically discuss the concerns expressed by Mr. Frye in his correspondence with Senator Mark Warner, Ms. Talbot provided an overview and answered questions from the Workgroup. She indicated that floor plans are required of everyone, including chain pharmacies, as is providing Social Security Numbers of employees, and that CVS Caremark is consistent in their credentialing process.

Oversight of PBMs by Virginia Department of Health Office of Licensure and Certification (VDH OLC)

Mr. Jones indicated that if the Workgroup recommended that VDH OLC would be the agency to provide oversight, they would be agreeable, but resources must come with it.

Mr. Musselman indicated that more than one agency may need to provide oversight. For example, defining "specialty drug" would be more appropriate under the Board of Pharmacy.

Next Meeting

Dr. Brown indicated that the next meeting will be on December 16 from 9am to Noon. Any comments may be sent to Dr. Brown's attention.

Topics to be discussed at the next meeting will include:

- White-bagging and Brown-bagging
- Waste involved in mail order

A draft report will be developed by DHP staff to be reviewed and discussed at the next meeting. It should include definitions of terms such as white-bagging, brown-bagging, specialty drug.

The meeting was adjourned at 2:10pm.

Prepared By: Laura Z. Rothrock

Report of the Pharmacy Benefit Managers Workgroup

Virginia Department of Health Professions

Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Association of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

Introduction:

In a letter from United States Senator Mark R. Warner dated February 19, 2015, the Virginia Board of Pharmacy was requested to look into a constituent's concern involving pharmacy benefit managers (PBM) and provide an appropriate response. The constituent requested that Senator Warner assist him with concerns regarding pharmacy benefit manager oversight as the Virginia State Corporation Commission, Bureau of Insurance, and Board of Pharmacy had informed him that they did not have legal authority to oversee or act on his complaint. The constituent alleged CVS Caremark and other PBMs discriminate against independent pharmacies by requiring documentation during the credentialing and re-credentialing process that are not required of chain pharmacies. He stated refusing to provide the documentation will result in a termination of the contract with the PBM for reimbursement of prescriptions. The constituent indicated that the un-level playing field threatens the survival of independent pharmacies and their ability to conduct normal business.

In a letter dated February 24, 2015 on behalf of the Board Chairman, the Executive Director for the Board of Pharmacy, after speaking with a representative of the Bureau of Insurance, confirmed to Senator Warner that neither agency have the authority to license PBMs or address the concerns expressed by the constituent. The letter indicated that there appears to be a possible lack of oversight in state law in regulating pharmacy benefit managers and that the board would discuss the issue further at its next meeting in March 2015.

At the March 24, 2015 Board of Pharmacy full board meeting, the Board heard comment from the National Community Pharmacists Association, the Medical Society of Virginia, the Virginia Pharmacist Association, EPIC Pharmacies, and owners of two independent pharmacies. Concerns included: lack of oversight of PBMs; impact PBM decision-making may have on patient access to medications, particularly in a rural setting; burdensome credentialing and re-credentialing processes that lack standards and demand too much of the pharmacist's time; PBMs' ability to designate drugs as specialty drugs and requiring them to be dispensed by mail order pharmacies often owned by PBMs; concerns with mail order pharmacies complying with statutory requirement for a bona fide pharmacist-patient relationship; and, an exclusion during the 2015 General Assembly session in HB 1942 and SB 1262 of the Bureau of Insurance to adjudicate patient disputes or disagreements regarding denial of access to medications by insurance carriers or the PBMs with which the carriers contract. Commenters requested that the Regulation Committee of the Board of Pharmacy further review concerns with patient safety, medication access, and determine if registration or licensure of PBMs is recommended. A 2013 report of the National Association of Boards of Pharmacy which considered the issue of regulation of PBMs was provided by the Medical Society of Virginia for the Board's consideration. Following deliberation, the Board concluded that some of the concerns do not fall within the Board's jurisdiction, but that the issue should be referred to the Regulation Committee for a more thorough review.

The Regulation Committee of the Board of Pharmacy considered this matter on May 11, 2015. Public comments provided to the Committee addressed concerns with patient safety based on an inability to obtain prescribed drugs in a timely manner and an increasing number of drugs requiring prior authorizations or being classified as specialty drugs which require dispensing

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, the Committee recommended that David Brown, D.C., Director of the Department of Health Professions (DHP), or William A. Hazel Jr., MD, Secretary of Health and Human Resources form a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Common approaches in the industry for PBMs to mitigate the high costs of drugs is to require prior authorizations of certain drugs or require certain drugs to be dispensed from a specialty pharmacy.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. PBMs currently determine which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug, and the specialty pharmacies are often owned or have a financial relationship with the PBMs.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the PBM. The primary purpose of the prior authorization is to decrease overall healthcare costs by ensuring the patient is receiving the least expensive, yet most effective drug therapy. PBMs determine which drugs require prior authorization, and this status can vary daily based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are usually informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human

Resources Management. There is no state oversight for self-insured health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) oversees fully-insured health plans, but not the PBMs with which they may contract to fulfill certain functions. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies, but not require it unless the PBM deems the drug a specialty drug which must be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, a complaint system in place, etc. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs.

Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

"White bagging and brown bagging"
This is a relatively new business practice that has been evolving over the past several years. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and, the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans
Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These

individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right.

Prior Authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drug up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated the general goal for processing prior authorizations, once the required information is received, is within 24 hours for emergencies and 48 hours for non-emergencies. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to payers for drug utilization management, e.g., identifying prescribing errors and mitigating the significant increase in drug costs imposed by pharmaceutical manufacturers, but that improvements to the prior authorization process are needed.

The Workgroup also identified the current model as a reactive prior authorization process and acknowledged that patients, prescribers, pharmacists, health plans, and PBMs would benefit from a more proactive process. Online resources for prescribers to determine drug coverage at the point of prescribing was briefly discussed, but challenges with time and accuracy of information create barriers to this solution. The National Adoption Scorecard for Electronic Prior Authorization from covermymeds® was reviewed and discussed. There was general consensus that the proactive process with electronic prior authorizations would significantly reduce the amount of time for all involved in handling prior authorizations and reduce the time delay in patients having access to the prescribed drugs. The Workgroup acknowledged that electronic prior authorizations cannot be utilized until electronic prescribing is commonplace. New York will be the first state to require all prescriptions to be electronically transmitted as of March 2016, and there is interest in monitoring the success of this requirement. In the interim, there was consensus that the Medical Society of Virginia along with the Virginia Pharmacists Association should meet with Virginia Health Plans and other key stakeholders to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future.

Credentialing process

Comment was received from several independent pharmacy owners, including the pharmacist who wrote Senator Warner, that the credentialing process is overly burdensome, lacks standards regarding the process and frequency at which they occur, and impacts patient care by reducing the pharmacist's time available for patient care. The process often involves verification of state licensure, DEA registration, National Provider Identification number, valid Medicare participation, valid pharmacist-in-charge, liability coverage, review of any disciplinary action, and review of state and federal tax files. In response to allegations in the letter to Senator

Warner that CVS Caremark discriminated against an independent pharmacy by requesting information from it that CVS Caremark did not request from chain pharmacies, a representative from CVS Caremark indicated it requests the same information from all pharmacies. There was discussion regarding why CVS Caremark needed a pharmacy floorplan, as this information is maintained confidentially by the Board of Pharmacy to reduce security risks. Presently, no uniform standards exist in State law regarding information which can be requested by a PBM during the credentialing and recredentialing process.

"Slamming"

Comment was received from independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacy Association regarding concerns for a new practice termed "slamming." "Slamming" occurs when PBMs call patients of specific pharmacies to encourage them to use a different pharmacy. Whether it is appropriate for PBMs to use their access to patient identification information for this purpose was called into question.

Filing complaints

There was some consensus that patients are generally unaware of who to contact or how to file a complaint regarding concerns with their drug coverage or access. Those members associated with health plans or PBMs reported that patients with employer insurance would have received this information in the insurance documents provided by the employer, however, it was suggested that perhaps this information should be more prominent or user-friendly. There was some discussion that complaints should be filed with the employer, but there was concern that many employers may not know how to address such complaints. As a self-insured health plan, the insurer for state employers has an ombudsman to receive complaints; however, Virginia does not have a designated ombudsman for addressing concerns with fully-insured health plans. VDH OLC and the BOI investigate matters after identifying a pattern of complaints but do not generally investigate individual complaints.

Appeal process

Fully-insured health plans are required to provide an appeal process for patients to lodge complaints, however, the process and timeframe for resolution may vary among plans or PBMs.

Impact on rural communities

Independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacy Association expressed concern that current PBM practices impact their ability to dispense prescriptions and are resulting in the closing of many independent pharmacies. One pharmacist indicated that 4 pharmacies have closed recently in his rural area and that patients must now drive 40 miles roundtrip to the nearest pharmacy. Because pharmacists are often the most accessible, if not the only, healthcare professional in rural settings, it was stated that healthcare questions may go unanswered, and compliance with optimal drug therapy may suffer. Independent pharmacies do not believe the current practices allow for a level playing field, as they feel PBMs are incentivized to drive business to the mail order and specialty pharmacies that have a financial relationship with the PBMs.

Recent actions regarding additional oversight
An antitrust attorney commented that the Federal Trade Commission is not adequately reviewing anticompetitive standards with current PBMs. He felt additional oversight of PBMs is warranted, because no one is currently looking after the patients' rights and that what the Workgroup is considering is very basic. There was discussion of the passing of an Iowa law impacting PBMs and a federal court judge's decision that ERISA does not preempt states from regulating PBMs. The decision is currently under appeal. It was stated that many states are taking reasonable reform action of PBMs and that recently 24 transparency bills and 23 audit reform bills were introduced across the states. Public comment was provided that simply licensing PBMs does not equal oversight and that enforcement powers are necessary.

The National Association of Boards of Pharmacy convened a task force in 2014 to review oversight of PBMs. It identified several tasks that may constitute the practice of pharmacy for which licensure and Board of Pharmacy oversight is appropriate. Presently, the Mississippi Board of Pharmacy is the only board of pharmacy to directly oversee PBMs. Based on Virginia's current model, there was discussion that it may be more appropriate to place potential oversight with the VDH OLC. VDH OLC is willing to assume this oversight if resources are provided.

Establishment of drug formularies
Express-Scripts indicated it uses a Pharmacy and Therapeutics Committee independent of the company to perform clinical reviews of drugs and make recommendations to the business side. If drugs are equivalent clinically, the PBM may negotiate with the manufacturers to determine the preferred drug. The PBMs and health plans stated that ultimately the employer determines what drugs will be covered.

Drug waste
Because mail order pharmacies typically dispense 90-day supplies, a concern was expressed that requiring or incentivizing patients to use mail order pharmacies may result in wasted drugs if the patient does not complete the entire course of medication.

Specialty drugs
There was much discussion regarding the increasing number of drugs being classified by PBMs as specialty drugs which must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy, and PBMs determine which drugs are specialty drugs. The practice was originally reserved for expensive or complex drug therapy, but presently it appears to be utilized more for cost control. Commenters in support of the process indicate the process helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Action Steps:

Below are potential actions that may be taken. There was general consensus for steps #1-4. Those representing pharmacists and pharmacies, along with VDH OLC, generally supported step #5. Those representing health plans and PBMs did not support #5; as they believe the health plans adequately oversee the PBMs, and no additional oversight is necessary

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.
3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should define the criteria for a specialty drug.
4. Because policy discussions often overlook the role community pharmacies play on improving patient care, particularly in a rural setting, it is recommended that future policy discussions include the impact that the closing of pharmacies would have on patient care in that environment.
5. Increase oversight of PBMs by VDH OLC with potential ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.