PSSNY
Pharmacists Society of the State of New York, Inc.

Statement of the Pharmacists Society of the State of New York

Department of Financial Services Public Hearing

CVS Health's Acquisition of Aetna, Inc.

Thursday, October 18, 2018

Superintendent Vullo thank you for conducting this hearing on the potential impacts on the delivery of health care and the health insurance market in New York State due to the pending acquisition of Aetna, Inc. by CVS Health that was recently approved by the US Department of Justice.

The Pharmacists Society of the State of New York (PSSNY) represents licensed pharmacists throughout the State of New York. The vast majority of our members work in community pharmacy and a significant number of them are pharmacy owners.

New York State has 2,325 independent pharmacies, representing over half of the pharmacies in New York State and 10% of the total independent pharmacies in the country. New York is ranked first in the nation for number of independent pharmacies. These local New York businesses generate more than $7.7 billion in pharmacy sales and create more than 21,000 full-time jobs. They fill nearly 139 million prescriptions each year and generate an additional $7.5 billion in economic activity and create 8,742 jobs outside the pharmacy in their local communities.[1] They are major contributors in their local communities and economies.

PSSNY is very concerned that increased vertical integration in the healthcare industry will contribute to higher costs, negatively impact patient choice, and drive community pharmacies out of business. PSSNY recommends that the acquisition of Aetna Inc. by CVS Health be closely examined and appropriately regulated to keep patients' healthcare access, costs and choices first and foremost. **ALL** patients have the right to affordable care with local healthcare providers. As this integration moves forward local pharmacies may no longer be able to compete with another large, integrated pharmacy benefit manager/insurer system that already has a dominate position in the market.

[1] *NCPA Digest 2017*, National Community Pharmacists Association.

Patient Access/Network Adequacy

The CVS Health/Aetna Inc. acquisition raises several questions regarding its impact on patient access to local pharmacies and network adequacy. A recent Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad,* found that just three pharmacy benefit managers (PBMs) account for 85% of the market.[2] CVS/Caremark, the PBM business for CVS Health, is the second largest PBM in the U.S., managing approximately 34% of covered lives.[3] This significant market share allows CVS/Caremark (as well as the other largest PBMs) to exercise undue market leverage and generate outsized profits for themselves. As a result, community pharmacies have very little negotiating power and are routinely forced to accept take-it-or-leave-it contracts to be part of the PBM's pharmacy network. In some cases, even if a pharmacy is willing to accept onerous contract terms, the PBM will simply exclude certain pharmacies from their networks altogether, limiting patient access and choice.

Aetna, for which CVS/Caremark administers the pharmacy benefit, has already engaged in this practice. The 2018 plan year marks the second consecutive year in which Aetna excluded many independent pharmacies from the opportunity to bid for preferred status in Aetna's Part D pharmacy networks. The opportunity to be a part of a plan's preferred network is critical for both pharmacies and beneficiaries, as nearly all Part D plans included preferred networks with lower co-pays.

On September 27, 2018, Aetna announced its agreement to sell its Medicare Part D drug plan business to WellCare, a subsidiary of WellCare Health Plans, pending DOJ approval. The irony is that WellCare utilizes CVS/Caremark as its pharmacy benefit manager. Therefore, post-acquisition, CVS Health retains control over both the pharmacy network and WellCare's Medicare Part D drug formulary.

The Aetna/Caremark/WellCare relationship offers a perfect example of the challenges present in the new vertically-integrated business model. It is impossible to control the conflicts of interest in the marketplace. The decision process for WellCare may follow a new pathway and the money may flow through different channels, but the result is the same. CVS Health will have access to more patient data and will control multiple revenue streams.

Merging a pharmacy/PBM with a health plan will only solidify problems with respect to pharmacy access issues, especially in underserved areas. PBMs like CVS/Caremark structure pharmacy benefits in ways that direct or incentivize patients into certain pharmacies. For example, the PBM can design the benefit to offer patients a lower co-pay for medications obtained at their own mail order pharmacy or retail stores and a higher co-pay at non-CVS community pharmacies in their network. An entity that controls the healthcare benefit as well as the prescription drug benefit inevitably will give patients even less control over choice and access.

[2] Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad*, Feb. 2018, *available at* https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

[3] According to CVS Health, it has 90 million PBM plan members. *See* CVS Health, *available at* https://cvshealth.com/about/facts-and-company-information. The Pharmaceutical Care Management Association testified that PBMs administer drug plans for more than 266 million Americans. *See* Testimony of Mark Merritt, Pharmaceutical Care Management Association, before the United States House of Representatives Energy and Commerce Committee Subcommittee on Health, "Examining the Drug Supply Chain," Dec.13, 2017.

CVS Health operates the largest pharmacy chain in the United States with approximately 9,700 retail locations and has significant share in many markets. Will the merged entity be able to use their dominant position to increase payments to CVS pharmacies? Conversely, will health plan competitors exclude CVS pharmacies from their plans adding to patient access woes? Will anyone know if they do?

For instance, will Aetna adopt a plan design that only allows Aetna members to access CVS' Minute Clinics or will Aetna raise costs to competitors who want access to the clinics for their beneficiaries? Will Aetna direct patients into CVS Minute Clinics rather than the primary care provider of the patient's choice? Will certain medical services be covered only at retail clinics? Will those patients also be incentivized to use the CVS pharmacy where the Minute Clinic is located? How much choice will patients actually have? Where do patients go to complain about lack of choice, unreasonable limitations or problems with the pharmacy benefit?

The new entity could require or strongly incentivize patients to use CVS Health's mail order and/or specialty pharmacies, exclusively, depriving patients of the services of a local pharmacist their treating physician knows and trusts. Patients, particularly those with more complex conditions that require specialty drugs, should have access to a pharmacist who sees them regularly and who provides ongoing professional services that support therapeutic goals of the prescribed medication.[4]

Recently, several HIV/AIDS patients sued CVS Health, alleging the pharmacy leveraged insurance laws to force patients to fill their prescriptions at CVS pharmacies or CVS Health's mail order company.[5] If the patient chose to obtain their prescription drugs from a different pharmacy, the patient faced thousands of dollars in costs to obtain the drugs. Other patients reported problems caused by lack of pharmacy choice. In one instance prescription drugs from CVS' mail order program had been left outside a patient's home, "baking in the afternoon sun."[6] Consistent, personal interaction with a pharmacist is proven to improve adherence which is especially important with chronically ill patients. The National Community Pharmacists Association (NCPA) has received over a hundred photographs of mail order waste from CVS and other mail order pharmacies in which millions of dollars of prescription drugs that were not needed or wanted were sent to patients. These patients seek out their local pharmacists' help in disposing these unnecessary and often costly drugs.[7]

Thus, there are serious questions as to whether patients will continue to have choice and access to their local pharmacists and primary care providers they prefer and whether quality and service will be compromised as a result of this giant healthcare entity.

[4] Smith, Marie, et al. *Why Pharmacists Belong in the Medical Home,* May, 2010, Health Affairs.
[5] Herman, Bob, Axios, *HIV patients sue CVS over pharmacy networks*, Feb. 21, 2018, *available at* https://www.axios.com/cvs-pharmacy-lawsuit-hiv-1519160365-c6f5527a-f5f2-429d-b817-6a9ea321335d.html; *see also John Doe One et al. v. CVS Health Corporation,* Case No. 3:18-cv-1031, N.D. Cal. (filed Feb. 16, 2018).
[6] Id.
[7] NCPA, *Waste Not, Want Not*, available at https://www.ncpanet.org/pdf/leg/sep11/mail_order_waste.pdf.

Formulary Construction

Another aspect of how much control CVS Health/Aetna will have on a patient's access to medications is its influence over coverage decisions. Formulary exclusion lists are an industry standard. By reserving the right to exclude certain medications from the formulary, PBMs gain leverage to negotiate steeper rebates and discounts from drug manufacturers for included medications. For patients, however, formulary exclusions can mean being denied coverage for a medically necessary and doctor-prescribed treatment. In 2017, 37% of denials for treatment of coverage for chronic illnesses were due to formulary exclusions.[8]

Chronically ill patients often choose a health plan because of the formulary list available during the open enrollment period. Formulary exclusion lists, once released annually, are now updated throughout a contract year. As a result patients are forced to change treatments after they have chosen a health plan suited to their medication needs.

Every time a patient's therapy is altered, particularly if the change is sudden, there is an increased risk of new side effects and drug interactions. If a patient chooses not to change treatments out-of-pocket costs could skyrocket. All of these factors contribute to decreased adherence or discontinuation of treatment that in turn can lead to complications, hospitalizations or permanent changes in health status that lead to increased costs.

Since 2012, CVS/Caremark has more than quadrupled the number of treatments it will not cover, from 38 to 183.[7] They were the first PBM to exclude some cancer medications. Other market-dominant PBMs soon followed.

On October 1, CVS/Caremark released its latest list of formulary exclusions. Although time has not permitted analysis of the newest changes, it is important to note that a significant number of injectable medications will be excluded in 2019. The patient populations most impacted are diabetic and behavioral health patients who tend to require the most counseling and support.

Patients' Healthcare Costs

The merging parties have stated that the proposed transaction will create efficiencies and save hundreds of millions of dollars for patients. They have not, however, explained whether those purported savings will be passed on to patients. The largest PBMs already claim their size enables them to achieve significant efficiencies and cost savings. As patients' out-of-pocket costs and premiums continue to rise, growing evidence suggests that these savings are not, in fact, being passed on to patients. Will savings from this acquisition be passed along? Did the 2012 merger of PBMs Express Scripts and Medco result in patient savings?

Patients that receive care at a CVS Minute Clinic that generates a prescription are likely to pick up their drugs at the CVS pharmacy. Will obtaining prescription drugs from a CVS cost the Aetna patient less? What will it cost non-Aetna patients? What about the cost to other health plans for prescriptions filled at CVS pharmacies?

[8] The Doctor-Patient Rights Project, *The De-List: How Formulary Exclusion Lists Deny Patients Access to Essential Care.* December 2017.

Will more patients be forced into mandatory mail order programs and how would that impact overall costs? It is a common misconception that steering patients into mail order will lower drug costs for consumers.[9] Evidence demonstrates that mail order pharmacies consistently dispense costlier brand-name drugs and fewer generics than retail pharmacies. As a "price giver" and a "price taker," mail order firms can manipulate pricing schemes. Plan Sponsors (employers, the federal government, individual purchasers) are often misled into thinking their overall prescription drug costs will be lowered by moving to mail order. At the end of the day, a shift to more mail order will lower the rate of generic dispensing, ultimately increasing overall drug costs. In comparison, community pharmacies dispense generics 88% of the time.

Medical Loss Ratio (MLR)

Recent scrutiny of PBM practices has uncovered a practice that directly impacts an insurer's Medical Loss Ratio (MLR) and provides plans the ability to improve their ratios and decrease or eliminate their rebates to patients, while actually increasing the costs of the pharmacy benefit plan.

Primarily, there are two payment models between PBMs and health plans. The first is a spread pricing model where the pharmacy is reimbursed for a dispensed drug and the health plan is charged a higher cost for that same dispensed drug. The PBM keeps the difference as part of its payment. In the second, less frequently seen model, the drug cost is passed through without a mark-up and the health plan pays an administrative fee for each processed claim.

If a PBM utilizes a spread pricing model in its health plan contract, the plan can account for its payments to the PBM as part of its medical claims, thereby improving its medical loss ratio; conversely, if an administrative fee is charged for every claim processed rather than a drug cost mark-up, the plan must account for that fee as an administrative expense, lowering the plan's MLR. Ironically, MLR was developed as part of the Affordable Care Act to provide better value to patients and to increase transparency, but the spread pricing model allows for a work around of the intent of the regulation while increasing the revenue of the PBM.

In an entity where both the PBM and health plan are under single ownership, how will this flow of pricing and fees be monitored? How will anyone know what is administration and what is the actual drug cost? Will the health plan be able to 'double dip' in reporting medical expenses and better improve its MLR and overall revenue?

States Scrutinizing Pharmacy Benefit Management in Medicaid

The Columbus Dispatch in Ohio has been conducting a months-long investigation into the rising costs of prescription drugs and the operations of PBMs through a series called *Side Effects*. Some of the key takeaways include the use of spread pricing (as explained above) by CVS/Caremark resulting in about $225 million in taxpayer funds going directly to the PBM. As CVS/Caremark was generating these profits it was simultaneously cutting pharmacies' reimbursement to the bone, often below the pharmacy's cost of the medication. As a result of these reports and a subsequent report from the Ohio State Auditor, the Ohio Department of Medicaid directed the state's five managed care plans (four of whom are managed by CVS/Caremark) to terminate any contracts using spread pricing models and

[9] *A Comparison of the Costs of Dispensing Prescriptions through Retail and Mail Order Pharmacies, available at* http://www.ncpanet.org/pdf/leg/feb13/comparison_costs_dispensing_prescriptions_retail_mail_order.pdf.

replace them with a transparent, pass-through model by January 1, 2019. As recently as September 16, it was reported that Ohio officials are concerned other loopholes in these contracts could allow for CVS/Caremark to offset its losses by manipulating the complicated drug-pricing system, potentially through rebates or other undiscovered methods.

In West Virginia, an actuarial study showed that the state could save $30 million annually by moving away from a managed care model back to a fee-for-service model—effectively eliminating the PBMs.

The Kentucky Department of Insurance in July issued an Order of Civil Penalty and Probation against CVS/Caremark for multiple violations of the Kentucky Insurance Code. As a result, Caremark's pharmacy benefit manager license was placed on probation for twelve months and Caremark was assessed a fine of $1,551,500. The Order cites four hundred fifty-four (454) violations related to reimbursement claim denials issued to pharmacists across Kentucky and an additional thirty-eight (38) violations where Caremark provided inaccurate or inconsistent information to the Department of Insurance.

Last fall in New York, pharmacists noticed a sudden, drastic drop in reimbursement as they dispensed generic medications and submitted claims for Medicaid Managed Care patients in the seven health plans managed by CVS/Caremark. Many pharmacies saw reimbursements of 40% or more **BELOW COST**. At that reimbursement rate, pharmacies could not replace inventory and with CVS/Caremark controlling 70% to 80% of prescriptions dispensed at these pharmacies, many anticipated closing their doors.

New York State law provides pharmacies a process to appeal these below cost reimbursements for generic medications. The law has been blatantly ignored. One single pharmacy has record of over 700 appeals that went unanswered.

New York's unenforced law created an opening for a brazen move by CVS Health. The sudden, drastic drop in reimbursement brought many independent pharmacies to the breaking point. *Unbelievably, pharmacies in this weakened state received offers from CVS Health to purchase their stores due to the dismal reimbursement environment – an environment they had created.*

These examples highlight the common business practices of today's market-dominant PBMs and the clear need for state regulation to protect New York patients and improve drug cost transparency and accountability. Burying PBM activities into a larger entity accomplishes the exact opposite.

Recommendations

As the healthcare system continues to consolidate, healthcare costs continue to increase, and patients have fewer choices, it is imperative that patients and providers are offered protection and a pathway to resolve issues created by large corporations, particularly those that merge healthcare, health insurance and prescriptions drugs and benefit design.

The Pharmacists Society of the State of New York strongly urges the Department of Financial Services to create a robust infrastructure to regulate pharmacy benefit managers starting with the licensure and registration of any entity that performs the functions of a PBM. Within that structure, the following is needed:

- reporting functions to analyze and track formulary adequacy to assure patient access to medications
- reporting functions to analyze and track network adequacy to assure patient access to pharmacies and other providers
- reporting requirements to ensure that co-pays are not being used as an incentive to steer patients to PBM-owned subsidiaries
- auditing authority for the department to ensure that there is fair reimbursement to providers, determine if there is manipulation of costs that impacts the plan's MLR and to fully understand how spread pricing is impacting patient costs
- a grievance process for patients, pharmacists and other providers to file complaints about the activities of PBMs to be investigated by state authorities
- creation of a PBM-funded emergency reserve fund that would be utilized in case of a health plan or PBM failure