PCMA 2020-21 State Budget Testimony before the Joint Legislative Hearing on Senate Finance and Assembly Ways & Means Committees

January 29, 2020

Good morning Chairwoman Krueger, Chairwoman Weinstein, Health Committee Chairs Rivera and Gottfried, and Committee members. I am Lauren Rowley, the Vice President of State Affairs for the Pharmaceutical Care Management Association (PCMA) of New York. PCMA is the national association representing America's pharmacy benefit managers (PBMs).

PBMs administer prescription drug plans for more than 266 million Americans. In NY, we administer prescription drug plans not just on behalf of health plans, but for hundreds of self-funded unions, school boards, municipalities, and employers across this State. These are entities in your communities, with limited budgets, who depend on PBMs to manage their drug benefits and their cost. Our ability to perform our services effectively have real life implications for them, their members, and their families.

A recent article highlights this point. Last Spring, the Altamont Enterprise, a small weekly paper right here in the Capital District--reported on a critical Budget issue in the Voorheesville School District. The high cost of specialty drugs for a handful of the District's members had blown a hole through the District's $1 million dollar drug budget, and was quickly burning through their entire reserve. The District's Drug Plan contracted with a PBM, but chose to have an open formulary, which did not prefer more cost effective and equally effective drugs over others, or maintain any other mechanism to control cost. Ultimately, to address their deficit the District was forced to lay off six employees, including a full time kindergarten teacher. The District is now working on moving all of its employees into managed formulary plans.

PBMs are on the frontlines working to maintain access and affordability. Tools like formulary management, and policies that promote lower cost therapies over more expensive ones, were not invented by PBMs. But as you can see, they are relied upon by millions of New Yorkers to mitigate the high cost of specialty maintenance drugs.

The same holds true for accreditation of specialty pharmacies. Accreditation is the industry standard for ensuring safe and quality dispensing of the specialty medications and biologics referenced in the article. PBMs play no role in the accreditation process. But it's critical to understand that all payers—from the State's NYSHIP Plan down to the Voorheesville School District, require and expect the pharmacies in their networks, that are dispensing high cost specialty drugs and biologics, meet the highest standards of quality and clinical expertise, to protect the safety of their members. This makes accreditation essential.

We hope this article helps highlight the fallacies of the narrative that is so often repeated, that you're helping consumers by attacking drug management performed by PBMs. The reality is, **when you impact the ability of a PBM to safely and effectively manage prescription drugs, all New York consumers are affected.**

Budget 2020-21

1. **PBM Licensure, Regulation, and the Need for Transparency of the Entire Drug Chain**

The Governor has reintroduced his licensure and regulation proposal we opposed in 2017-18, and again last year. We continue to have serious concerns with this proposal. **However, as a general matter, PCMA does not oppose licensure, regulation, and transparency**. Our member's earnings statements are public record. PBM profit margins are in the low single digits. We are not the reason drugs are so expensive—that starts and stops with the drug maker's themselves.

PCMA believes there should be transparency of all actors in the drug chain. In our view, much of the legislature's rightful focus on consumers and drug prices has been misdirected by special interests acting in their own self-interest. For example, the prevailing narrative being told is PBMs are putting Independent Pharmacists out of business in NY. We believe this is false, and objective data bears this out. According to independent data from Quest Analytics, the number of independent pharmacies in NY increased from 2,185 to 2,813 between 2010 and 2019. That is 29% growth. Pharmacist salaries in NY continue to be the highest in the country. And a recent study by the Georgetown University Center on Education and the Workforce that ranked 4,500 colleges and universities based on return on investment and value of your degree found the top 3 schools in the country were all Pharmacy Colleges, followed by MIT and Stanford. Albany College of Pharmacy was #1 in the nation.

Put simply, the State should not be relying on stories and anecdotes to inform health care policy. There should be full transparency of all entities in the drug channel so decisions are made based on objective data.

2. **Medicaid Budget Deficit**

When the pharmacy benefit was carved in to managed care under MRT I, PBMs helped save an estimated $200 million per year according to DOH estimates (2012). PCMA and our member companies look forward to continuing our work with the State to meet its fiscal and policy goals. PCMA is eager to help the State find solutions to address the current Medicaid Budget Deficit. We believe there is an opportunity to produce immediate savings through better fraud, waste and abuse oversight. We've included some recent highlights on the OMIG page of pharmacy fraud in the NY. PCMA member companies have reason to believe there is a lot more fraud that is currently going on that could be detected and prevented through reasonable changes to current law. We look forward to discussing these with you and the MRT. Thank you.

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THE ALTAMONT ENTERPRISE
NEW SCOTLAND

VCSD prescription-drug plan caught in a nationwide trend of soaring prices

Tuesday, April 30, 2019 - 14:17

VOORHEESVILLE — Across New York State, school health-care costs continue to outpace both the rate of inflation and allocation of state aid, with costs rising 22 percent between the 2013-14 and 2017-18 school years, from $5.8 billion to $7.1 billion.

Enterprise file photo — Melissa Hale-Spencer
Francis Rielly, *Voorheesville's assistant superintendent of finance and operations, said that the district's current prescription-drug plan has no mechanism for containing costs; whatever the price of the drug, the district has to pay it. Those cost increases led to a large budget deficit, which led to the loss of jobs.*

In the Capital Region, over those four years, health-care costs grew by over 26 percent.

This year, Voorheesville's self-funded prescription-drug plan, after years with barely any increase, saw a 35-percent spike in its prescription-drug costs, which led to deep budget cuts to balance next year's school budget. The district's drug plan is not tied to its health-insurance plan; it's a separate premium set by the district's pharmacy benefit manager, Express Scripts.

The district has already blown through its million-dollar prescription-drug budget for the year, and is burning through a $681,000 reserve that, as of the beginning of this month and not including the most recent bill, had about $380,000 left in the account; however, the current number is lower.

The high-cost biologic and maintenance drugs "buried us," Francis Rielly, Voorheesville's assistant superintendent of finance and operations, told The Enterprise last week.

Biologics, which are not made like typical drugs, are very costly and, coupled with the lack of government oversight, leave Americans paying more for their prescription drugs than residents in any other wealthy nation.

The problem for Voorheesville, Rielly said, is that the district is enrolled in what he called a "basic" formulary drug plan, which has no mechanism for containing costs; whatever the price of the drug, the district has to pay it.

The basic formulary plan, Rielly said, is the pharmaceutical package that is offered to member districts of the Capital Area Schools Health Insurance Consortium (CASHIC), a health-insurance trust made up of 19 school districts in the Capital Region.

Rielly and other CASHIC members were told by representatives from Express Scripts, the health-insurance trust's pharmacy benefit manager, that the primary drivers of cost increases were biologics — drugs produced from living organisms or their components — and specialty drugs. A pharmacy benefit manager negotiates prices with drug

manufacturers on behalf health plans of all kinds: government, private, and employer-based.

In addition to the cost increases brought on by biologics, Rielly said that the district was also paying for brand-name drugs for which there are generic equivalents available, but, because of the setup of the district's basic formulary plan, Voorheesville will continue to pay through the nose for brand-name drugs.

At the meeting with Express Scripts, Rielly said, the CASHIC members were told that, to lower prescription-drug costs, the school districts should move to managed formulary plans, "because then you are negotiating prices."

A managed formulary plan is a preferred list of drugs that, according to Express Scripts, "carefully exclude[s] medications in an effort to negotiate better rates on behalf of [Express Scripts] clients," and, "opens access to all clinically superior medications, while eliminating 'me-too' options that have no added clinical benefit but have higher costs. And as a result, drug makers are compelled to charge fair prices for the medication they manufacture."

The managed formulary plan, Rielly said, has cost-saving restrictions — like step therapy, prior authorization, and quantity limits — that are not part of the district's current basic formulary plan.

Step therapy — also called "fail first" — is a process where a patient would start with a less expensive, generic drug, and, if that doesn't work, would then move up to a more-expensive brand-name drug. Prior authorization, according to the American Medical Association, is "any process by which physicians and other health-care providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage."

These cost-saving restrictions have also been criticized for hindering patient care.

Over the next six months, Rielly said, the district will look into placing all employees into a managed formulary plan. The seven members of the administrators' union recently agreed to a new contract, which included an agreement for the union to enter into a managed formulary plan, which starts Oct. 1.

But no matter what options Rielly is able to find, a change in plan coverage still has to be negotiated with the district's two other bargaining units: the United Employees of Voorheesville, which represents non-instructional workers, and the Voorheesville Teachers' Association.

The UEV just signed a five-year agreement, but Rielly said that the contract can be reopened for "a particular item," if there is cause, "and certainly there would be cause for that to happen."

And the district continues to negotiate with the teachers' union; its contract ran out in June 2018.

Right now, though, Rielly said that he is gathering information on a drug plan from the Board of Cooperative Educational Services that covers about 60,000 people, whereas the

current CASHIC plan that Voorheesville is part of covers about 20,000. “It sounds like they are getting good prices,” Rielly said of the BOCES drug plan.

However, the BOCES plan is still experienced-based, Rielly said, so the quote that the district would receive would be based on the sky-high prices that the district is currently paying for prescription drugs.

Going to a managed formulary plan, Rielly said, “is what we need to do for the long-term health of the district,” which, he added, is why the administrators' union got on board.

Voorheesville’s current drug plan is damaging the budget and costing employees their jobs, he said, adding that the most recent bill Voorheesville received for prescription drugs was $87,678, which was for a two-week period — the district budgeted $89,500 for the entire month.

The high-cost biologic and maintenance drugs “buried us,” Rielly said.

Biologics

Biologics are derived from living material — a sharp contrast from conventional drugs which are “chemically synthesized” and “have a well-defined structure and can be thoroughly verified,” according to the United States Food and Drug Administration.

Scientific American describes the process of “growing” biologics:

“In a factory just outside San Francisco, there’s an upright stainless steel vat the size of a small car, and it’s got something swirling inside.

“The vat is studded with gauges, hoses and pipes. Inside, it’s hot – just under 100 degrees Fahrenheit. Sugar and other nutrients are being pumped in because, inside this formidable container, there is life.

“Scientists are growing cells in there. Those cells, in turn, are growing medicine. Every two weeks or so, the hot, soupy liquid inside gets strained and processed. The purified molecules that result will eventually be injected into patients with Stage IV cancer.

“Drugs that are made this way – inside living cells – are called biologics.”

In broad strokes, what differentiates chemical compounds from biologics is the size and make up of the molecules.

Conventional drugs are made up of small molecules that act as an inhibitor, blocking a person’s symptoms, like someone plugging a whole in a dam with a finger.

Biologics have large molecules that have the ability to bind to the molecules in a person’s body, which can inhibit a person’s symptoms, according to Scientific American, but biologics also have the ability to “stimulate the immune system in a problem area, like at a tumor, prompting the body to take it out.”

Costs

Americans pay more for their prescription drugs than citizens of other countries because there is no government entity that regulates the cost of prescription drugs, whereas around the world many governments step in to regulate drug prices.

As recently as the turn of the century, Americans were paying approximately the same for prescription drugs as their counterparts among the world's wealthiest countries.

Then, between 1997 and 2007, spending on prescription drugs in the United States tripled, according to a study in Health Affairs. Spending around the world increased as well but not nearly as rapidly.

In 1997, for example, per-person spending for pharmaceuticals in the United States was about $285; by 2015, that number became about $1,011.

Switzerland, which in 1997 paid about $206 per person for pharmaceuticals, by 2015, had a per-capita spending of about $783. Sweden was the lowest per-capita spender in 2015, at $351 per person.

At the heart of the spending increases is biologics.

Twelve of the 15 best-selling prescription drugs in the United States in 2018 were biologics.

About 2 percent of the United States population "is treated with a specialty drug each year — a category that includes biologics and other complex, often expensive drugs," according to a report from the RAND (Research ANd Development) Corporation. Yet, in 2018, according to Express Scripts, specialty drugs accounted for about 52 percent of total drug spending. And biologics, specifically, made up between 27 and 40 percent of total drug spending, according to the White House Council of Economic Advisers.

Humira, a biologic, is not only the best-selling prescription drug in the United States but around the world as well. AbbVie, the maker of Humira, has doubled the drug's price from $19,000 annually in 2012 to about $38,000 today.

In the early 1990s, for example, the most expensive drug sold was Taxol, which was used for treating breast cancer and cost $4,000 per year, according to Health Affairs. By comparison, Herceptin, a biologic used in treating breast cancer, cost $27,990 per year in 2009, when the Health Affairs study was written.

To be clear, biologic drugs have been very successful in treating major chronic diseases, like cancer and auto-immune diseases.

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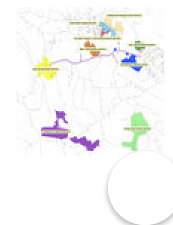

- 86-year-old Voorheesville man flips car

When first responders arrived at the scene of an accident in Feura Bush on Tuesday, they found a car on its roof and the 86-year-old driver trapped inside.

- ### Voorheesville's first filing in Stewart's lawsuit seeks dismissal of all claims

Stewart's announced in September 2019 it was suing Voorheesville, claiming the village was targeting the company to keep it from building a new shop in the village. The village, in its first response to the lawsuit, asked that the suit be tossed.

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OMIG Assists in Investigation that Leads to Arrests of NYC Pharmacy Owner, Managers for Roles in Alleged $10 Million Medicaid Scheme

July 22, 2019

A New York City pharmacy owner and three of her managers were arrested July 19 following an OMIG-assisted investigation for their alleged participation in a multi-million-dollar Medicaid fraud scheme involving kickbacks and HIV prescription drugs.

Irina Pichkhadze, 34, of Queens, NY, the Owner of First Choice Pharmacy in Harlem, NY, and three of her managers, Raymond Dieffenbacher, 46, of Queens, NY, Yana Dubrinskaya, 31, of Brooklyn, NY, and Tarlan Pinkhasov, 40, of Queens, NY were charged by prosecutors in State Supreme court with two counts of Grand Larceny in the First Degree, two counts of Health Care Fraud in the First Degree, and Scheme to Defraud in the First Degree for defrauding Medicaid out of more than $10 million in an alleged kickback and HIV prescription drug diversion scheme.

According to prosecutors with the state Attorney General's Medicaid Fraud Control Unit (MFCU), the defendants directed employees to pay cash kickbacks to Medicaid recipients, in return for each patient's agreement to fill their HIV prescriptions at Pichkhadze's First Choice Pharmacy, which generated hundreds of thousands of dollars from Medicaid.

Prosecutors further allege that between 2013 and 2016, Pichkhadze's First Choice Pharmacy filed thousands of false claims for reimbursement from Medicaid and Medicaid Managed Care Organizations (MCOs) in refills that were not dispensed, as evidenced by its not purchasing enough medication from licensed New York State drug wholesalers to justify the quantities of medication it claimed.

Pichkhadze, Dieffenbacher, and Dubrinskaya were also charged, along with two additional companies - Express Audit and OTC - with various counts of money laundering in the first and second degree in connection with the scheme; Pichkhadze was also charged with two counts of Criminal Possession of a Forged Instrument in the Second Degree. Grand Larceny in the First Degree, Health Care Fraud in the First Degree, and Money Laundering in the First Degree are all class "B" felonies for which the maximum state prison sentence is 25 years. Money Laundering in the Second Degree, Criminal Possession of a Forged Instrument in the Second Degree, and Scheme to Defraud in the First Degree are, respectively, class "C", "D", and "E" felonies carrying maximum prison terms of 15, 7 and four years.

OMIG pharmacy consultants and investigators assisted in the investigation, along with officials from the New York State Department of Health and United States Department of Health and Human Services, Office of the Inspector General (HHS-OIG).

The charges and allegations contained in an indictment are merely accusations. The defendants are presumed innocent unless and until proven guilty.

View more about these charges as well as OMIG's assistance.

New York State Office of the Medicaid Inspector General

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UPDATE: Manhattan Pharmacist Accused of Stealing Millions From Medicaid in HIV Prescription Drug Fraud Scheme Sentenced to Prison Term

March 15, 2019

A Manhattan pharmacist arrested in 2017 following an OMIG-assisted investigation for defrauding the Medicaid program more than $3 million via an HIV prescription drug fraud scheme was sentenced March 15 to two to six years in state prison.

Hin T. Wong, 50, of Manhattan, the owner of three Manhattan pharmacies in connection with the multi-million-dollar Medicaid fraud scheme, was sentenced by Manhattan Supreme Court Justice Mark Dwyer after pleading guilty Feb. 22 to Grand Larceny in the First Degree. Wong additionally forfeited more than $3.6 million as restitution to the New York State Medicaid program.

Wong was arrested in 2017 after the joint investigation determined Wong fraudulently billed Medicaid and Medicaid Managed Care Organizations more than $3.6 million for HIV drugs from January 2014 to August 2017. Wong later admitted that she directed her employees to pay kickbacks to several undercover agents in return for their agreement to fill their HIV prescriptions at her pharmacies, as well as not purchasing a sufficient inventory of medication from licensed drug wholesalers to account for the pharmacies' medication quantities.

View more about this story as well as OMIG's efforts.

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