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Report from The Interagency Pharmaceuticals Purchasing Study Group

Established by HCR 35 of the 150th General Assembly

I. General background on healthcare costs and the cost of pharmaceuticals

“The U.S. is alone among other high-income countries in not exercising some kind of government leverage over drug prices.”

Healthcare Industry Expert

a. Scope of work

There are many opportunities to reduce the cost of pharmaceuticals for every Delawarean regardless of their insurance or if they are uninsured, but this Study Group’s scope of work is limited to Medicaid, State Employee Benefits, Department of Correction, Delaware Veterans Home, Delaware Psychiatric Center, Delaware Hospital for the Chronically Ill, and any other state agency or department that contracts or purchases pharmaceuticals. The Study Group’s work does not include Medicare nor any private insurance pharmaceutical programs.

b. Health care in Delaware

This year Delaware taxpayers will spend \$1.4 billion on health care, primarily on state employee / retiree benefits and Medicaid. Health care now accounts for 30.6% of our total State budget; second only to our expense in education. According to the Kaiser Foundation, Delaware’s per capita cost for healthcare is the 4th highest in the nation; just below the District of Columbia, Alaska, and Massachusetts. Further evidence provided by the Commonwealth Fund indicates that Delaware’s 2018 overall health system performance is ranked 22nd compared to all other states. Cost and quality represent the most basic measurements of a health care system. Cost over quality equals the value of any health care system. If Delaware is the 4th highest in cost and 22nd in performance, then our State’s overall value of health care is much lower than it should be. There are many reasons for this result, most of which are outside the scope of this Study Group, but the cost of pharmaceuticals is undoubtedly a

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contributing factor. Lacking effective action on a federal level, Delaware must take action to reduce the continuing high cost of drugs. In a recent article published in JAMA entitled “Healthcare Spending in the United States and Other High-Income Countries,” the authors provide evidence of contributing factors that support America’s high cost of health care. Their conclusions are listed below:

Conclusions

The United States spent approximately twice as much as other high-income countries on medical care, yet utilization rates in the United States were largely similar to those in other nations. Prices of labor and goods, including pharmaceuticals, and administrative costs appeared to be the major drivers of the differences in overall cost between the United States and other high-income countries. As patients, physicians, policymakers, and legislators actively debate the future of the U.S. health system, data such as these are needed to inform policy decisions.

As the conclusion of this article states, “As ... legislators actively debate the future of the U.S. health system, data such as these are needed to inform policy decisions.” The facts must guide us. As this Study Group explores its charge of investigating pharmaceutical costs, many essential points in this article are crucial:

1. America has the highest overall pharmaceutical spending per capita than any of the other 11 countries surveyed. America’s per capita expenditure was \$1,443 compared to the global mean of \$749.
2. America’s retail spending per capita is \$1,026 compared to the global mean expenditure of \$541.

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3. America's prices are more than double the next highest amount for brand-name medications for the treatment of cholesterol, diabetes, and asthma.
4. America has the lowest percentage of public spending on pharmaceuticals [Medicare and Medicaid] and the highest percentage of private expenditure.

c. Pharmaceuticals

Pharmaceuticals account for 10-12% of U.S. total health care costs, but 21% of employer insurance benefits with an out-of-pocket cost to beneficiaries of \$47 billion. In 2017, U.S. retail prescription drug cost spending was \$333 billion. Types of drugs with the highest out-of-pocket cost include medications that are called "specialty drugs." These are very different from their forebears, both in effectiveness and in cost. They are high tech, high cost, are targeted to a very small percentage of patients – particularly in oncology – and they account for a much larger share of the overall cost. It is not unusual for a specialty drug to have a total treatment cost per patient of \$100,000.

Over the next decade, prescription drug costs could see the fastest annual growth ever, rising an average of 6.3% per year. This increase is due to higher prices and more use of specialty drugs such as those for genetic disorders and cancers.

Pharma's influence with policymakers is substantial. According to data compiled by the Center for Responsive Politics, an independent group that tracks money in politics, drug manufacturers spent \$171.5 million for lobbying the federal government on pharmaceuticals ... more than insurance, oil, gas, or any other industry.

II. Membership and purpose

a. Members

- Representative Ray Seigfried – Co-Chair | State Representative, District 7
- Senator Nicole Poore – Co-Chair | State Senator & Senate Majority Leader, District 12
- Victoria Brennan | Chief of Fiscal Policy, Office of the Controller General

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- Matilde Cruz | Advanced Practice Nurse, Division of Public Health (succeeded by Tony Ward | Quality Assurance Administrator, Division of Public Health)
- Stephen Groff | Director, Division of Medicaid and Medical Assistance
- Terry Hollinger | Administrator, Delaware Veterans Home (succeeded by Archie Poling | Director of Nursing & Acting Administrator, Delaware Veterans Home)
- Dr. Richard Margolis | Medical Director, Department of Services for Children, Youth & Their Families
- Commissioner Trinidad Navarro | Insurance Commissioner, Department of Insurance
- Senator Brian Pettyjohn | State Senator, District 19
- Faith Rentz | Director, Statewide Benefits and Insurance Coverage
- Dr. Marc Richman | Bureau Chief of Correctional Healthcare Services, Department of Correction (succeeded by Jim Elder | Bureau Chief of Correctional Healthcare Services, Department of Correction, replaced by Michael Records | Deputy Bureau Chief of Correctional Healthcare Services, Department of Correction)
- Representative Michael Smith | State Representative, District 22
- Dean Stotler | Director of Government Support Services, Office of Management and Budget
- Secretary Dr. Kara Odom Walker | Cabinet Secretary, Department of Health and Social Services

Participants

- Dr. Jeromie Ballreich | Director of the Masters in Health Economics and Outcomes Research Program & Assistant Scientist, Johns Hopkins Bloomberg School of Public Health
- Representative Andria Bennett | State Representative, District 32

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- Steven Costantino | Director of Healthcare Reform, Department of Health and Social Services
- Dr. Trevor Douglass | Oregon Prescription Drug Program & Pharmacy Purchasing Director, Oregon Health Authority
- Frederick Gibison | Partner, Mercer Government Human Services Consulting
- Deborah Gottschalk, Esq. | Legislative Attorney, Division of Research
- Leslie Ledogar, Esq. | Regulatory Specialist, Department of Insurance
- Dr. Awele Maduka-Ezeh | Medical Director, Department of Correction
- Joana Nassa | Partner and East Market Pharmacy Leader, Mercer Government Human Services Consulting
- Dr. Hooshang Shanehsaz | Director of Pharmacy, Cardinal Health
- Dr. Janine Statt | Senior Government Consultant, Mercer Government Human Services Consulting
- Dr. Abigail Stoddard | Senior Government Consultant, Mercer Government Human Services Consulting

Staff

- Scott Murphy Eisenhart | Legislative Aide, Representative Ray Seigfried
- Taylor Hawk | Executive Assistant, Senate Majority Leader Nicole Poore

b. Purpose of the Study Group

The price of pharmaceuticals is a significant driver of the high cost of our health care system. As good stewards of taxpayer money, we have a responsibility to ensure that we reduce the cost of this valuable resource. The Study Group's primary outcome is the following:

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1. To research and evaluate opportunities to leverage the bulk purchasing of pharmaceuticals on an inter-agency level in Delaware to negotiate lower prices.
2. To make recommendations regarding the most beneficial method to leverage the bulk purchasing of pharmaceuticals in Delaware with a multi-state consortium.
3. To make legislative changes that support the reduction of pharmaceutical prices, especially on an inter-agency level throughout state government.

III. The current state of operation

a. Delaware Medicaid pharmaceutical purchasing

Delaware's Medicaid program has two primary service components. The Division of Medicaid administers fee-for-service (FFS) benefits and Medical Assistance (DMMA), and reimbursements are made directly to providers. DMMA provides monthly capitation members to one of two Managed Care Organizations (MCOs) who administer managed care benefits.

Medicaid FFS payments are made to pharmacies for the costs of drugs dispensed to Medicaid beneficiaries. Drug costs are a factor of ingredient costs, dispensing fees, and drug rebates. The federal government requires states to use the actual acquisition cost (AAC) to set payment rates. National Average Drug Acquisition Cost (NADAC) data is used to measure AAC. States have the flexibility to establish a reasonable professional dispensing fee. In most cases, Delaware Medicaid's FFS dispensing fee is \$10 per prescription. The dispensing fee for certain specialty drugs and clotting factor is \$27.

Federal law requires manufacturers of drugs covered under Medicaid to participate in the federal drug rebate program. Medicaid programs must cover almost all FDA-approved drugs produced by these manufacturers. States may also negotiate supplemental rebates in addition to the federal statutory rebates and establish preferred drug lists (PDL). A PDL differs from a drug formulary in that Medicaid programs may not deny a non-preferred drug if it is medically necessary for the beneficiary. Delaware participates in the Sovereign States Drug Consortium (SSDC). The SSDC is a multi-state purchasing pool to negotiate supplemental drug rebates.

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Managed care pharmaceutical purchasing is administered by pharmacy benefit managers (PBMs) under contract to the MCOs. The MCOs negotiate pharmacy reimbursement rates but are contractually prohibited from negotiating rebates. DMMA continues to invoice for drug rebates directly for drugs purchased for MCO beneficiaries. The MCOs and FFS Medicaid also have an aligned PDL.

Total pharmacy spending for Calendar Year 2018 was \$244,142,800 before rebates. Over 40% of this spending was for specialty drugs, which accounted for only 1% of paid claims.

b. State of Delaware Group Health Insurance Program (GHIP) prescription benefits & services

The State Employee Benefits Committee (SEBC) has statutory authority over plan design and cost-sharing for prescription benefits provided to employees, non-Medicare, and Medicare retirees and covered dependents participating in the GHIP. These benefits are administered by a Prescription Benefit Manager (PBM) through two plans; a commercial program for employees and non-Medicare retirees and an Employer Group Waiver Plan (EGWP) for Medicare retirees and spouses. Prescription benefits and services for the GHIP are competitively bid out, and the SEBC is currently negotiating the fifth and final year of a contract with the current PBM, Express Scripts, for an effective date of July 1, 2020 (FY21). The SEBC will release a Request for Proposals in August 2020 for a new contract award and the effective date of July 1, 2021 (FY22).

PBM services include claims processing, formulary management, pharmacy network, mail order, specialty pharmacies, negotiation of price, discount and rebates with pharmaceutical manufacturers and pharmacies, drug utilization review, disease management, and adherence initiatives.

In FY19, the GHIP projected plan costs, net of rebates, were \$184.2 million. Approximately 85% of a day's supply of medications filled by GHIP members were in the retail pharmacy setting. Specialty medications comprised about 35% of plan costs compared to 37% for governmental peers. GHIP member's use of generics undoubtedly is on par with peer groups at 84%, and the use of the 90-day maintenance network is running at 73% compared to governmental peers at 46%.

Renegotiation of the FY20 contract will take place for a one-year extension. Other considerations to address as the SEBC prepares a re-procurement of these services for FY22 include the impact of overall plan costs on purchasing select drugs / services from another source, compliance with the Centers for Medicare and Medicaid Services

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(CMS) for administration of the EGWP plan, resources needed to administer existing prescription drug benefits, and member impact / disruption resulting in any change to the current prescription benefit structure.

c. Department of Correction

The Department of Correction has a contract with Correct RX for pharmaceutical products and a full line of services. Correct RX provides prescription fulfillment, 24/7 delivery of the product, and five on-site pharmacists. They also participate in a multi-state buying group called Innovatix Premier.

d. Delaware Veterans Home

The Delaware Veterans Home contracts with Pharmerica Services for both pharmaceutical products and services. Pharmerica Services provide prescription fulfillment, delivery of the product, and an on-site pharmacist.

e. Delaware Psychiatric Center

The Delaware Psychiatric Center (DPC) Pharmacy purchases medication through a State contract with Cardinal Health. The Pharmacy participates in the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) Infuse, a national cooperative group purchasing organization (GPO) for government facilities. Purchases from Cardinal Health are based on the current hospital formulary and medication orders from providers for the inpatient client population. The majority of the pharmaceutical purchases are through MMCAP Infuse and are for contracted items for a reduced cost. The Pharmacy also conducts pre-packaging into unit-dose using bulk supplies of oral medications to further reduce medication costs. The average monthly purchases for the Pharmacy amount to approximately \$70,000.

f. Delaware Hospital for the Chronically Ill (DHCI)

The Division of Services for Aging and Adults with Physical Disabilities (DSAAPD) purchases prescription medications used in our Long-Term Facilities (DHCI & Governor Bacon Health Center) directly utilizing the interagency multistate purchasing organization MMCAP Infuse. The Division purchases with transparent

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discounted prices negotiated by the GPO from manufacturers. The GPO also has a share back program based on purchases. The Division utilizes services such as prescription fulfillment, 24/7 delivery of the product, and four on-site pharmacists.

IV. State strategies to reduce the cost of pharmaceuticals

Introduction

The Study Group recognizes that the strategies listed in this section are directed at the price of drug products. Some departments also engage in pharmaceutical services like on-site pharmacists, delivery, inventory, dispensing, drug reports, and many other important services from Pharmacy Benefit Managers (PBMs) and companies that affect the price of the drug. These services need to be explored as well for improvements together with the price of the drug.

Several cost reduction strategies that focus on price were reviewed and considered. Some of these strategies are outlined below:

1. limiting drug price increases through the use of an international pricing index.
2. “favored nation clause,” where federal law would restrict drug companies from selling to other countries lower than the U.S.
3. taxing drug companies that increase their price over an established percentage figure.

Most of these strategies need a federal law to work, and given the current situation on a national level, it is unlikely that any legislation would be passed. The Study Group reviewed additional strategies that states have tried. The policies that we discussed in more detail are provided below.

a. Importation of pharmaceuticals

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Some states like Utah are currently engaged in purchasing medications from Canada and Mexico and, in some cases, providing patients transportation to these countries to purchase pharmaceuticals at a lower price. The current presidential administration has supported this action. Though the law allows states to apply to the federal government to import drugs, there are many exceptions, including controlled substances, injectable medications known as biologics, and insulin. On the surface, this strategy seems good until one understands the details.

To begin with, the reason why most other countries have lower drug prices is that their governments leverage their purchases by negotiating directly with the manufacturer. Second, there is no guarantee of what is called “chain of custody,” which ensures that what is purchased is indeed ultimately delivered. One of the significant responsibilities of the FDA is patient safety, and the previous FDA commissioner raised concerns about counterfeit products. In fact, in March of 2019, the FDA announced that a Canadian drug distributor - CanaRx - was selling unapproved and mislabeled medicines to unsuspecting Americans looking to save money on prescriptions. Finally, Canadian officials have warned the U.S. government that importation programs could jeopardize their own supply of drugs, leading to potential shortages. Drug companies have also said that importation programs could result in higher prices for those countries that participate. The Study Group did not believe that this would be effective.

b. Transparency and disclosure of manufacturer drug costs

This strategy would require drug manufacturers to provide their costs of manufacturing drugs. The federal government tried to enforce this by having drug companies identify their drug costs in TV commercials, but the courts overruled based on First Amendment rights. The intent of this is more to shame drug companies by showing the wide gap between their costs and prices on the market. California passed a law requiring drug companies to provide advance notice of price increases and specific reasons for the rise. Pharmaceutical Research and Manufacturers of America challenged this law in court and won. Shedding light on the complex supply chain of pharmaceuticals would expose pharmacy benefit managers (PBMs), spread pricing, rebates, anticompetitive practices, and many other techniques used by the manufacturer to control prices. The Study Group felt that this would be an effective way to show the complex supply chain, but not the best to reduce costs.

c. Engage in bulk and pooled purchasing

Using an economic principle called “economies of scale,” savings occur by lowering the cost of production due to an increase in the number of products produced. This strategy is the one used behind the “Elijah E. Cummings Lower Drug Costs Now Act” (HR 3 of 2019) which passed the House of Representatives, allowing the Centers for Medicare & Medicaid Services (CMS) to negotiate directly with drug companies and is currently before the

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Senate. In a Kaiser Family Foundation poll, 85% of Americans (both Republicans and Democrats) want the government to negotiate directly with drug makers.

Delaware, like many other states, already uses bulk and pooled purchasing to some extent, but implementing this across the whole State using inter-agency volume remains an opportunity for savings. This action favors smaller states that lack a large amount of purchasing and could be a substantial opportunity if several states joined forces. Both the Veterans Administration and Kaiser Permanente Health Plans use this strategy to negotiate and have obtained steep discounts from drug companies.

One primary challenge is to pool both Medicaid and non-Medicaid populations into a single purchase. The Medicaid Drug Rebate Program (MDRP), a federally mandated program, provides states with both mandated discounts and limits on how they can structure prescription drug coverage. Under the MDRP, states are required to cover all FDA-approved drugs with few exceptions. In exchange, pharmaceutical manufacturers are required to offer state Medicaid programs rebates that ensure that Medicaid's payment for any drug product matches or exceeds the "best price" in the market. The requirement to provide all FDA approved drugs limits the State government's ability to negotiate with manufacturers and design coverage in a way that directs patients to the most cost-effective therapies. Delaware, as most states do, utilizes a "preferred drug list", which helps to nudge patients towards a preferred drug. But the federal Department of Health and Human Services has the authority to grant waivers to allow states to pilot and evaluate innovative approaches to serving beneficiaries. CMS has recently approved requests from several states to negotiate drug prices for Medicaid based on their effectiveness and value.

Opportunities do exist by utilizing bulk volume in many ways. States can pool their Medicaid volume together and use data analytics to evaluate certain drugs that could be used more effectively on their "preferred drug list." Non-Medicaid drug purchasing would benefit because knowledge of these prices would help in negotiation for State employees, correction, and other departments. Additionally, sharing with other states would provide a learning experience to compare and contrast not only prices but also services and drug programs to make improvements. Utilization of spread prices, rebates, and agreements with the pharmacy benefit manager would also be a significant learning opportunity for growth. Based on a review of alternative strategies, the Study Group recommends this one as the recommended direction.

V. Findings, recommendations, and legislation

a. Findings

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- The Study Group recognizes that drug prices in some cases may be a part of a total contract for pharmaceutical services. As an example, some departments contracting for medication also need services like on-site pharmacists, delivery, inventory, dispensing, drug reports, and many other important services from Pharmacy Benefit Managers (PBMs) and companies that affect the price of the drug. These services need to be explored as well for improvements together with the price of the drug.
- Departments manage pharmaceuticals on an individual function level. They are siloed from a collective level in maximizing their potential volumes for further price reduction opportunities. Currently, drug price measured performance is based on internal benchmarks from previous years.
- Data analytics across all departments managed by an independent consultant will enable us to have knowledge of everyone's current situation and be positioned to advance in obtaining lower prices.
- As a small state, even with total consolidation, our volume would not be enough to affect a significant market price reduction. The State may achieve substantial price reductions through an alliance with other states in a multi-state bid for products and services.

b. Recommendations

- Legislate a commission called *The Interagency Pharmaceutical Purchasing Collaborative* to fully leverage the State's purchasing power and regulatory authority to maximize savings for Medicaid, State Employee Health benefits, and all other agencies and departments that contract for or directly purchase pharmaceuticals. The Collaborative will have representation from the departments and a working group for analysis of information. The Department of Health and Social Services (DHSS) will provide administrative support through the position of a Pharmacist who will work with the consultant. DHSS will fund both the data analytics software and consultant. The State will own the data, and the consultant will report to the Collaborative.
- The consultant will consolidate all State pharmaceutical prices and services into a data analytic profile to build a market database. The Collaborative will have its working groups assess the value (cost and patient outcome) of individual drugs, and with the volume from the States interagency volume combined with a multi-state consortium, negotiate directly with manufacturers to obtain an overall lower price.
- Identify opportunities to leverage inter-agency pharmaceutical purchasing that may include joining with a state consortium, Group Purchasing Company, or other opportunities.
- Create and implement a standard transparency clause for all contracts and purchases for pharmaceuticals covering the manufacturer, the Pharmacy Benefit Manager, and all other companies throughout the supply chain.

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- The Collaborative will maintain a working relationship between agencies that purchase pharmaceuticals, including the State Employee Benefits Committee (SEBC), the Division of Medicaid and Medical Assistance, and the Department of Correction.
- Explore providing a public pharmaceutical contract offering to Delawareans through a not-for-profit participating program.

c. Legislation

AN ACT TO AMEND TITLE 29 OF THE DELAWARE CODE RELATING TO PHARMACEUTICAL PURCHASING.

Respectfully submitted January 24, 2020