SB20-107: Drug Production Costs Transparency Analysis Report

Concerning an analysis of prescription drug manufacturer data on high-cost prescription drugs paid for by specified state departments to determine the components of the production process that drive the price of the prescription drugs.

Details

Bill Sponsors: House – Mullica (D) and Jackson (D)
            Senate – Ginal (D)
Committee:   Senate Health & Human Services
Bill History: 1/15/2020- Introduced
Next Action:  2/6/2020- Hearing in Senate Health & Human Services
Fiscal Note:  2/3/2020

Bill Summary

The bill establishes the “Prescription Drug Production Costs Transparency Act of 2020.” The Department of Health Care Policy and Financing (HCPF) is to collect, analyze, and report prescription drug production cost data regarding the 20 highest-cost prescription drugs per course of therapy and the 20 highest-cost prescription drugs by volume that were purchased or paid for by the Department of Corrections (DOC), Department of Human Services, Department of Personnel and Administration (DPA), and HCPF. Manufacturers are required to report to HCPF the components that drive the wholesale acquisition cost (WAC) of the drugs on the list.

Issue Summary

Prescription Drugs in the U.S.

Recently there has been renewed attention on the cost of prescription drugs and the increase of their prices over the past decade. There were more than 5.8 billion dispensed prescriptions in 2018.1 Approximately 58 percent of Americans report that they are currently taking at least one prescription drug while 25 percent take four or more prescription drugs.2 From 2017 until 2026 prescription drug spending is anticipated to increase 6.3 percent per year.3 According to the Centers for Medicare & Medicaid Services (CMS), $325 billion was spent on retail prescription drugs in 2015.4 Net per-capita spending was $876 per person in 2017 and increased to $1,044 in 2018.1 Out-of-pocket costs for patients was an estimated $61 billion in 2018, but each patient’s exposure to these costs varied dramatically.5 For example, 8.8 percent of patients pay more than $500 for their prescriptions.1 A 2015 Consumer Reports poll found that 30 percent of people who take at least one prescription drug a month had unexpected spikes in the out-of-pocket cost of their drug(s) in the

past year. Additionally, one in eight Americans report that either they or their family member has cut pills in half or skipped doses due to high drug costs.

**Prescription Drugs in Colorado**

In 2018, nearly 42.5 million prescription drugs were filled at pharmacies in Colorado, resulting in $6.02 billion of retail sales. On average, there are approximately 10.8 medications dispensed per year per person in Colorado; of those, 8.7 are generic medications. According to the Colorado Health Institute’s (CHI) 2019 Colorado Health Access Survey, 10.8 percent of Coloradans cite the cost of prescription drugs as reason for not filling the medicines they are prescribed. Another study by CHI found that in 2015 the median out-of-pocket expenditures on prescription drugs was $149 per year. However, median prices do not tell the whole story; some individuals and families can have high cost burdens for out-of-pocket costs for prescriptions. What an individual pays for medications is dependent on factors like their condition, type of insurance, and cost sharing requirements. A majority, 82 percent, of Colorado voters think that the cost of prescription drugs are too high. The same survey also showed that 89 percent of respondents agreed with the statement, “The public should have the right to know the costs that are factored into the price of prescription drugs and medications to ensure fair and ethical business practices.”

In the 2016 Community Health Survey conducted by the Health District of Northern Larimer County, 8.6 percent of adult residents within the Health District reported being unable to have a prescription filled because they could not afford it during the preceding two years. This rate is much higher among those who reported being uninsured (28 percent).

**Brand-Name Drugs**

The FDA utilizes a structured framework for the approval all new brand-name drugs. To grant approval, the agency conducts an analysis of the target condition and other treatments in the market for the condition, assesses the benefits and risks of the drug, and evaluates risk-management strategies. From preclinical testing to approval, the average length of time for a new drug is 12 years. An analysis by IQVIA found that the increase in spending on drugs during 2016 was mainly driven by new brands and price increases for those drugs that are still under patent protection. Brand-name drug prices nearly doubled in price from 2008-2016. However, in 2017 brand-name net prices increased by an average of 1.9 percent, which is below

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9 This approximation utilizes data from the Center for Improving Value in Health Care (CIVHC), which does not reflect the uninsured, some people covered by self-insured employer plans, and those covered under Federal programs like TRICARE, Indian Health Services, or Veterans Affairs (VA).
13 With a 95% confidence interval ranging from 7.3% to 10.0%.
the rate of inflation.\textsuperscript{17} The list price (wholesale acquisition cost [WAC]) of the average brand-name drug increased from $308.77 in 2013 to $415.78 in 2017. The average final out-of-pocket costs, including after the use of manufacturers coupons to offset the cost, was $42 per brand prescription in 2018.\textsuperscript{18} In the same year, 19 percent of patients on commercial insurance used coupons to reduce their out-of-pocket costs.

Generic Drugs
Generic drugs are identical to their brand-name counterparts and work in the same manner. These generics must be approved by the FDA and can only go to market after the patents and regulatory exclusivities have expired for the brand-name drug. In 2017, approximately 90 percent of retail prescription drugs filled were generics.\textsuperscript{19} Also, they were dispensed 97 percent of the time it was possible to do so.\textsuperscript{19} Generics are typically sold at prices that are 80 to 85 percent less than the cost of a brand-name drug.\textsuperscript{20}

Specialty Drugs
The definition of a specialty drug is highly dependent on the entity utilizing the phrase, thus the definition can vary widely. One organization, the IQVIA Institute, defines it as a drug that treats a complex, chronic, or rare disease, and has at least four of the following characteristics: list price over $6,000 per year, maintained by a specialist medical provider, not self-administered, requires special handling in supply chain, requires patient payment assistance, distributed through non-traditional channels, and/or has significant side effects that require patient monitoring.\textsuperscript{21} For 2019, Medicare defines a specialty tier drug as one that costs more than $670 per month.\textsuperscript{22} The anticipated growth in prescription drug spending over the next decade is largely attributable to a larger percentage of that spending on specialty drugs.\textsuperscript{23} Specialty drug spending was $87 billion in 2012, representing 25 percent of total drug spending and 3.1 percent of total health care spending in the U.S.\textsuperscript{24} Specialty drugs accounted for 46.5 percent of drug spending in 2017, a dramatic increase from 2012.\textsuperscript{25} In 2017, spending has shifted greatly to specialty medicines, driving nearly 82 percent of the net growth of new brands on the market. The use of specialty medicines grew by 5 percent in 2018, more than double the rate of other drugs.\textsuperscript{26}

Wholesale Acquisition Cost (WAC)
Also known as list price, the wholesale acquisition cost (WAC) is similar to a suggested retail price created by the manufacturers for wholesalers or direct purchasers and is only occasionally relevant to the pricing of both generic and brand-name drugs.\textsuperscript{27} Thus, the WAC is not based on any actual sales of a drug. It is defined in federal Medicaid statute as “the manufacturer’s list price for the drug or biological to wholesalers or direct

\begin{itemize}
\item \textsuperscript{20} FDA (Jan. 2018). Generic Drugs: Questions & Answers. Retrieved from https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm#q4
\end{itemize}
purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.\textsuperscript{28} The WAC serves as a basis for negotiations between entities in the supply chain.

Research and Development

Pharmaceutical research and development is an expensive process, with some estimates of the cost of this innovation being as high as $5.5 billion spent per successful drug that makes it to market.\textsuperscript{29} Once the drug has been researched, developed, and approved by the FDA, the manufacturing costs of the drug are relatively low.\textsuperscript{31} The market exclusivity granted to brand-name drugs by patents and regulatory action allows these manufacturers the chance to recoup their initial investment before competition from generic medications can influence the cost of the drug. It is estimated that a successful brand-name drug must have $1.5 billion in revenues each year to cover the capital costs for research and development.\textsuperscript{31} However, the exact amount that the manufacturers spend on research and development for a specific drug and its revenue on that drug is difficult to determine. The following chart from HCPF’s report, “Reducing Prescription Drug Costs in Colorado” generally delineates the total revenue and spending for large pharmaceutical companies in 2014.\textsuperscript{30}

<table>
<thead>
<tr>
<th>Company</th>
<th>Total Revenue ($bn)</th>
<th>R&amp;D Spend ($bn)</th>
<th>Sales and Marketing Spend ($bn)</th>
<th>Profit ($bn)</th>
<th>Profit Margin (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson (US)</td>
<td>71.3</td>
<td>8.2</td>
<td>17.5</td>
<td>13.8</td>
<td>19</td>
</tr>
<tr>
<td>Novartis (Swiss)</td>
<td>58.8</td>
<td>9.9</td>
<td>14.6</td>
<td>9.2</td>
<td>16</td>
</tr>
<tr>
<td>Pfizer (US)</td>
<td>51.6</td>
<td>6.6</td>
<td>11.4</td>
<td>22.0</td>
<td>43</td>
</tr>
<tr>
<td>Hoffmann-La Roche (Swiss)</td>
<td>50.3</td>
<td>9.3</td>
<td>9.0</td>
<td>12.0</td>
<td>24</td>
</tr>
<tr>
<td>Sanofi (France)</td>
<td>44.4</td>
<td>6.3</td>
<td>9.1</td>
<td>8.5</td>
<td>11</td>
</tr>
<tr>
<td>Merck (US)</td>
<td>44.0</td>
<td>7.5</td>
<td>9.5</td>
<td>4.4</td>
<td>10</td>
</tr>
<tr>
<td>GSK (UK)</td>
<td>41.4</td>
<td>5.3</td>
<td>9.9</td>
<td>8.5</td>
<td>21</td>
</tr>
<tr>
<td>AstraZeneca (UK)</td>
<td>25.7</td>
<td>4.3</td>
<td>7.3</td>
<td>2.6</td>
<td>10</td>
</tr>
<tr>
<td>Eli Lilly (US)</td>
<td>23.1</td>
<td>5.5</td>
<td>5.7</td>
<td>4.7</td>
<td>20</td>
</tr>
<tr>
<td>AbbVie (US)</td>
<td>18.8</td>
<td>2.9</td>
<td>4.3</td>
<td>4.1</td>
<td>22</td>
</tr>
</tbody>
</table>

\textbf{Figure 11. Total Revenue And Spending By Category, Top 10 Pharmaceutical Firms, 2014.}

In order to receive sufficient financial investment for the development of a new drug, manufacturers have to compete to attract and engage both private and public investors. The largest government investments in

\textsuperscript{28} 42 USC § 1395w-3a(c)(6)(B)
drug discovery research have come from the National Institutes of Health (NIH); but, states also are increasingly investing state funds in this arena.\textsuperscript{31}

**Medicaid & Prescription Drugs**

Although coverage of outpatient prescription drugs is an optional benefit under federal law, all states have opted to provide such coverage.\textsuperscript{32} Federal law allows states create policies that allow pharmacies to collect a ‘nominal’ copayment from enrollees.\textsuperscript{33} The actual amount of funds spent by the program on outpatient prescription drugs is the payment to the pharmacy minus the rebates Medicaid receives from drug companies. The Medicaid Drug Rebate Program (MDRP) was created as a part of the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508).\textsuperscript{34} Those manufacturers that opt to participate in the MDRP are required to offer state agencies that administer the program a rebate of at least 23.1 percent of Average Manufacturer Price (AMP)\textsuperscript{35} for a brand-name drug, or the best price.\textsuperscript{36} Although MDRP participation is technically voluntary, it is essentially mandatory as manufacturers that decline to participate are not only excluded from Medicaid but all other federal programs, such as Medicare and the Department of Veterans Affairs.\textsuperscript{37} This program is not just beneficial for the Medicaid program; in exchange, states are required to include that manufacturer’s drugs in their formulary.\textsuperscript{38} Funds that are collected under the MDRP are shared between the state and the federal governments based on the state’s federal matching rate.\textsuperscript{39} Generic and brand-name drugs have different rebate formulas.

Most states have opted to negotiate supplemental rebates from manufacturers.\textsuperscript{40} Some of these states do so as a single unit while others have created multi-state groups for these negotiations in order to have greater leverage. Manufacturers that enter into supplemental rebate agreements do so in order to get their products placed favorably on the state’s formulary.

Prescription drug spending under the entire Medicaid program reached a zenith in 2014 as spending increased 24.6 percent from the prior year, this increase slowed slightly in 2015 to 13.6 percent.\textsuperscript{41} In fiscal year 2015, Medicaid spent $53 billion in payments to pharmacies but received $24 billion in rebates.\textsuperscript{42} The graph from HCPF demonstrates Colorado’s Medicaid prescription drug spending over time.\textsuperscript{42}


\textsuperscript{33} 42 U.S. Code § 1396o


\textsuperscript{35} The AMP represents the average price that is actually paid to manufacturers by wholesalers and direct purchasers and includes some rebates. Defined in federal Medicaid statute (42 USC § 1396r-8 (k)(1)) as “the average price paid to the manufacturer for the drug […] by wholesalers for drugs distributed to retail community pharmacies; and retail community pharmacies that purchase drugs directly from the manufacturer” including “discounts, rebates, payments, or other financial transactions” but not including customary prompt pay, rebates/discounts to certain entities (i.e. pharmacy benefit managers, managed care organizations, health maintenance organizations, clinics, etc.) and other exclusions. Confidential price.

\textsuperscript{36} Health Affairs. *Prescription Drug Pricing: Medicaid Best Price*.

\textsuperscript{37} The Council of Economic Advisors. Reforming Biopharmaceutical Pricing at Home and Abroad.

\textsuperscript{38} MACPAC. *Medicaid Payment for Outpatient Prescription Drugs*.

\textsuperscript{39} Ibid.

\textsuperscript{40} Ibid.

\textsuperscript{41} Ibid.

This Legislation

“Comprehensive list” means the list of prescription drugs compiled by the Departments. The bill defines “course of therapy” as either the recommended daily dose of a drug for a 30-day treatment or a normal course of treatment that is less than 30 days, pursuant to the FDA-approved package insert. “Departments” means the Department of Corrections (DOC), Department of Human Services (DHS), Department of Personnel and Administration (DPA), and Department of Health Care Policy and Financing (HCPF).

“Manufacturer” means a person, holding company, parent company, or other affiliate that manufactures a prescription drug made available in Colorado. The “wholesale acquisition cost” is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.”

HCPF, or a contractor, is to collect, analyze, and report prescription drug production cost data. The Department or its contractor is to collect applicable data from the All-Payer Claims Database (APCD), Division of Insurance (DOI), Departments, and any other relevant sources. If HCPF utilizes a contractor, the contractor must demonstrate it is qualified for the task and has no financial interest in and is not connected with any prescription drug manufacturer, insurance carrier, or entity/person that has a financial interest in the outcome of the analysis. The General Assembly is to appropriate money from the General Fund to support these activities.

By December 1, 2020, and each December 1 after, the Departments are to jointly compile a comprehensive list containing the names and WACs for the following drugs that each purchased or paid for during the previous state fiscal year:

- 20 highest-cost prescription drugs per course of therapy
- 20 highest-cost prescription drugs based on volume of the drug purchased/paid for

The Departments will provide this information to HCPF or its contractor to perform the required analysis.

By February 1, 2021, and each February 1 after, HCPF or its contractor is to submit a written request to each manufacturer for information showing the basis for and components of the WAC of each drug on the comprehensive list that the manufacturer produced. It is to include the following information:

- Research and development costs
- Clinical trial costs
- Regulatory costs
- Costs for materials, manufacturing, and administration attributable to the prescription drug
- Income from other entities, including grants, subsidies, or other support that offsets the research and development, clinical trial, or other development costs
- Cost to acquire the technology associated with the drug or the rights/ownership of the drug from a third party
- Patent and licensing costs
- Promotional marketing costs, including direct-to-consumer advertising

Within 120 days after receiving a written request, but no later than June 1 of that year, the manufacturer is to provide HCPF or its contractor full and complete documentation showing the basis for the WAC of each drug on the list that is produced by that manufacturer.

After receiving the information from the manufacturers, HCPF or its contractor is to analyze the documentation to determine the basis for each drug’s WAC. A report is to be prepared to detail the findings for each drug and specify the percentage of WAC that is attributable to each component that is driving the WAC.

43 42 USC § 1395w-3a(c)(6)(B)
By December 1, 2021, and each December 1 after, HCPF or its contractor is to provide a final prescription drug production cost transparency report on the drugs contained in the comprehensive list to the House Health and Insurance Committee, House Public Health Care and Human Services Committee, Senate Health and Human Services Committee, and Joint Budget Committee.

The reporting requirement continues indefinitely.

HCPF and the contractor must maintain confidentiality of all proprietary information obtained from a manufacturer. Any proprietary information is exempt from the Colorado Open Records Act (CORA).

The Executive Director of HCPF may adopt rules to implement and administer this bill.

A manufacturer that fails to report requested information is subject to a civil penalty of up to $10,000 per day for each day that it fails to report the information. The Executive Director of HCPF is to report violations to the Attorney General. The Attorney General and the District Attorneys are authorized to institute appropriate proceedings to prosecute the matter.

The bill takes effect July 1, 2020.

Fiscal Note
The fiscal note states that the bill requires an appropriation to HCPF totaling $250,000 for state fiscal year 2020-2021. The funds are assumed to be needed in order to secure a contractor to collect and analyze the state agency comprehensive list along with the manufacturer information.

Reasons to Support
This bill could help clarify what prescription drugs cost for each respective department, while keeping the manufacturers accountable to what components lead to the prices they set. The prescription drug production cost transparency report could allow policymakers to see if there are certain common factors driving the pricing of prescription drugs that the state spends money on. Derived from the transparency, further legislation may be able address some of the drivers of the cost.

Supporters
- AARP
- America’s Health Insurance Plans
- Colorado AFL-CIO
- Colorado Children’s Campaign
- Colorado Community Health Network
- National Multiple Sclerosis Society
- RxPlus Pharmacies

Reasons to Oppose
The bill mandates manufacturer reporting, some of which could be proprietary. It states that such information is to be kept confidential; however, some of that information could be essential to creating a robust report that actual details the components that drive the pricing of those drugs on the comprehensive list. Therefore, the report may not be as robust as intended.

Further, the mandated cost driver information from the manufacturers may be of interest to state policymakers but many of those components may not be able to be regulated at the state level and instead require federal action.
Opponents

- Amgen
- Bristol-Myers Squibb
- Colorado BioScience Association
- Genentech
- GlaxoSmithKline
- Johnson & Johnson
- Novartis
- Novo Nordisk
- Pharmaceutical Research Manufacturers of America (PhRMA)

Other Considerations

Legal action on behalf of the manufacturers could occur if the entities believe that this report would undermine proprietary information. The cost of this legal action could require both monetary resources and staffing to defend the law in court.

It may be difficult to ensure that the costs that the manufacturer includes in each line item are actual expenses associated with that description. For example, it could be possible for a manufacturer to categorize some marketing and recruitment costs as research and development costs. Proponents may want to define, or allow the DOI to define through the rulemaking process, the costs that are allowed to be included in the “research and development” line item.

About this Analysis

This analysis was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. This analysis is accurate to staff knowledge as of date printed. For more information about this analysis or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.