


Date: February 28, 2018	POLICY ANALYSIS PREPARED FOR THE BOARD OF DIRECTORS	
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HB18-1260: PRESCRIPTION DRUG PRICE TRANSPARENCY

Concerning prescription drug price transparency.

Details

Bill Sponsors:	House – <i>Ginal (D) and Jackson (D)</i> Senate – <i>Moreno (D)</i>
Committee:	House Committee on Health, Insurance, & Environment
Bill History:	2/26/2018- Introduced in House- Assigned to Health, Insurance, & Environment
Next Action:	3/1/2018- Hearing in House Health, Insurance, & Environment

Bill Summary

This bill enacts new reporting requirements on both health insurers and prescription drug manufacturers. Health insurers must provide the Division of Insurance (DOI) with information regarding the prescription drugs that were covered by the insurer. The manufacturers must notify purchasers regarding increases in the wholesale acquisition cost (WAC) of prescription drugs and specialty drugs coming to the commercial market.¹ Furthermore, a manufacturer must provide a report, with defined content, to the DOI each quarter regarding the notifications to purchasers that the manufacturer was required to make. The information received in this report is mandated to be posted by the DOI to the department’s website. The DOI, or contractor, is to analyze the data received from both the insurers and manufacturers to determine the effect of prescription drug costs on premiums. The analysis should be compiled, posted on the DOI website, and reported to the relevant committees of the General Assembly. If a manufacturer does not comply, the DOI is to report violations to the state board of pharmacy, which has specified penalties to enact.

Background

The Challenge of Rising Costs of Prescription Drugs

According to the Colorado Health Institute’s (CHI) 2017 Colorado Health Access Survey, 10.7 percent of Coloradans cite the cost of prescription drugs as reason for not filling the medicines they are prescribed.² In the 2016 Community Health Survey conducted by the Health District of Northern Larimer County, it was found that 9 percent of residents within the Health District had been unable to have a prescription filled because they could not afford it during the preceding 2 years. This rate is higher among those who reported being uninsured (28%). Another study by CHI found that in 2015 the median out-of-pocket expenditures on prescription drugs was \$149.³

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.⁴ Additionally, specialty drugs repeatedly been found to be a driver of pharmaceutical spending.⁴ One such specialty drug that has been in the forefront since its introduction to the market in 2014 is the brand-name drug Harvoni, which is used to treat Hepatitis C. The cost of this drug has captured headlines since a course of therapy runs in the tens of thousands of dollars and is exponentially more expensive in the U.S. market than in other countries.⁴

¹ A specialty drug treats a complex condition, treats a rare disease, has enhanced storage or shipping requirements, or is not stocked at a majority of retail pharmacy.

² Colorado Health Institute (2017). *Colorado’s New Normal: Findings from the 2017 Colorado Health Access Survey*. Retrieved from https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/2017%20CHAS%20DESIGN%20FINAL%20for%20Web.pdf

³ Colorado Health Institute (2016). *Sticker Shock: Prescription Drug Affordability in Colorado*. Retrieved from <https://www.coloradohealthinstitute.org/research/sticker-shock-prescription-drug-affordability-colorado>

⁴ Kamal, R., & Cox, C. (2017). Peterson-Kaiser Health Systems Tracker. *What are the recent and forecasted trends in prescription drug spending?* Retrieved from <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-growth-prescription-spending-slowed-2016-increasing-rapidly-2014-2015> 2017.

Shading Denotes Changes from Analysis Dated 2/15/2018

Average price Harvoni, 28 tablets, 4-week supply, 2015

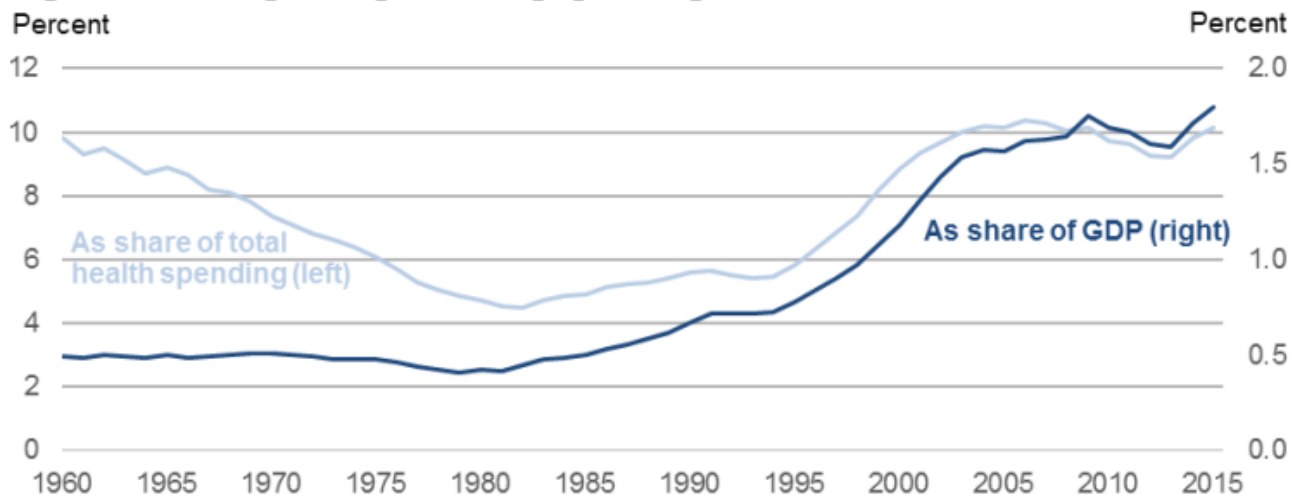


Source: International Federation of Health Plans 2015 Comparative Price Report • [Get the data](#) • PNG

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Prices of individual drugs have been high and/or increasing over the last decade and the cost of these drugs as a whole have been encompassing a greater share of health care costs and the country’s GDP.⁵

Figure 1: Retail prescription drug spending



Source: The National Health Expenditure Accounts, Centers for Medicare & Medicaid Services; BEA.

BROOKINGS

As the increase of prices of established drugs and the introduction of high cost drugs continues to make headlines in the U.S., the consumers are beginning to take more notice. The graphic below delineates how the public believes these prices should be lowered.

⁵ Olson, P. & Sheiner, L. (Apr. 16 2017). Brookings Institution. *The Hutchins Center Explains: Prescription drug pricing*. Received from <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>.

Percent who say they favor each of the following in keeping prescription drug costs down

Requiring drug companies to release information to the public on how they set their drug prices

86%

Allowing Medicare to negotiate with drug companies for lower drug prices

82%

Limiting the amount drug companies can charge for high-cost drugs for illnesses like hepatitis or cancer

78%

Allowing Americans to buy prescription drugs imported from Canada

71%

Source: Kaiser Family Foundation Health Tracking Poll (conducted Sept 14 – 20, 2016) • [Get the data](#) • [PNG](#)

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Prescription Drug Pricing

The distribution of pharmaceutical drugs is a chain of different buyers and sellers.⁶ This chain can include manufacturers, wholesalers, retail pharmacies, direct service pharmacies, pharmacy benefits managers (PBMs), and the actual consumer. A PBM negotiates the price paid to a pharmacy for a specific product on behalf of an insurer.

There are a variety of factors that influence the pricing of prescription drugs.⁷ First, manufacturers are hoping to recoup their spending not only on the production of the drug, but also on the research and development of the drug. Secondly, the amount of competition for the product is taken into account. When pricing the drug for consumer purchase, the bargaining power of the purchaser is taken into account and the demand from the consumers themselves. The typical marketing budget for a product is approximately a third of total revenue, so the projected cost of the marketing campaign will be taken into account. Finally, the cost of labor to manufacture the drug will affect the price; the location of manufacturing dictates overall labor costs.

The simplest model to explain the different prices in the chain (of a very complex system) includes the route from manufacturer to wholesaler, to the pharmacy, then ultimately to the patient.⁷ The price that the manufacturer sets is known as the wholesale acquisition cost (WAC). The WAC is publicly available from pricing services like Redbook or MediSpan. However, the WAC is not necessarily the price paid to the manufacturers by wholesalers. The average manufacturer price (AMP) is the actual average price paid to the manufacturer by wholesalers for drugs that will be distributed to retail pharmacies. The AMP is a confidential price. The average wholesale price (AWP) is a publicly available benchmark for pricing and reimbursement by both public and private payers. The AWP is not a representation of actual market prices but rather a “sticker price” that is more elevated than what is actually paid. The pharmacy discount price (PDP) is the price paid to the pharmacy by a program. What the patient actually pays is determined by the insurer or, if uninsured, the pharmacy, and typically includes an additional dispensing fee. The dispensing fee is a charge for the pharmacist’s services.

Other States’ Legislation

Recently many policymakers in state legislatures have introduced measures aimed at increasing the transparency of the cost of prescription drugs. These efforts have varied in their target within the chain (i.e.

⁶ National Health Policy Forum. (Aug 29, 2005). *Issue Brief #807: One Pill, Many Prices: Variation in Prescription Drug Prices in Selected Government Programs*. Retrieved from http://www.nhpf.org/library/issue-briefs/IB807_DrugPricing_08-29-05.pdf.

⁷ Espinosa, J. (2016). Lecture on Setting Prescription Drug Prices, George Washington University, Washington DC.

manufacturer or PBM). In California Senate Bill 17 (SB 17) was passed in October 2017, which generally mandates similar reporting requirements as this legislation.⁸ The California law requires manufacturers to notify purchasers and explain the rationale if they raise prices more than 16 percent in a 2 year period if the WAC is over \$40. The law penalizes noncompliant manufacturers with a civil penalty of \$1,000 per day. Furthermore, when a PBM receives the notice of the price increase, they must notify clients if the plan has more than 500 beneficiaries. Insurers must report the 25 most frequently prescribed drugs, most costly drugs, and drugs with the most increases on a year-to-year basis.

During the debate in the California's legislature, the industry's main association, Pharmaceutical Research and Manufacturers of America (PhRMA), worked hard to defeat SB 17; they hired 45 firms and spent over \$16.8 million lobbying activities.⁹ After the bill's passage, PhRMA changed its approach; on December 8, 2017, it filed for declaratory and injunctive relief in a U.S. District Court. The filing claims that the law violates the Dormant Commerce Clause, the First Amendment, and the Fourteenth Amendment's Due Process Clause.¹⁰ No decision has been reached yet in that case.

This Legislation

The Colorado bill would require that insurers include certain measures in their annual health care cost report starting on June 1, 2019. For all covered drugs used in an outpatient setting, health insurers must report the 25 most frequently prescribed drugs, most costly drugs by total annual plan spending, and the drugs with the highest increase in plan spending compared to the immediately preceding year. This information is to remain confidential, but will be analyzed by the DOI or a third-party for the report mandated below.

Starting on July 1, 2018, a manufacturer with a drug whose WAC is more than \$40 for a course of therapy must notify, in writing, all of its purchasers if the WAC is to increase more than 10 percent. This notification must be done 90 days prior to the actual increase and include the amount of the increase (in dollars), the cumulative increase over the past 2 years, the date of the increase, the current WAC, a statement about whether a change or improvement in the formulation in the drug requires an increase, and what the change was (if applicable). Manufacturers also have to notify purchasers if they are introducing a new specialty drug to the market within three days after its release. To aid in the notification of purchasers, the DOI should make a list of the purchasers.

Manufacturers must also report to the DOI within 15 days of the end of quarter certain information regarding any notifications of purchasers that occurred in that quarter. For notifications due to a WAC increase, the manufacturer must report descriptions of the factors (i.e. off-label use, changes in federal policy, cost of current treatments, etc.) that were utilized in the decision, a schedule of WAC increases in the past 5 years, gross revenues from sales in Colorado, and, as applicable, other specified details about the type of drug and previous drug ownership. For specialty drug notifications, the manufacturer must describe the marketing and pricing plan for the drug's launch, the estimated amount of patients that may be prescribed the drug for its approved use, whether drug was given special designations by the federal government during the review process, and the date of acquisition if they did not develop the drug.

⁸ California Legislative Information (2017). *Senate Bill No. 17*. Retrieved from http://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB17

⁹ Dembosky, A. (Oct. 10, 2017). National Public Radio. *California Governor Signs Law to Make Drug Pricing More Transparent*. Retrieved from <https://www.npr.org/sections/health-shots/2017/10/10/556896668/california-governor-signs-law-to-make-drug-pricing-more-transparent>.

¹⁰ Wolitz, R.E. (Jan. 6, 2018). Stanford Law School, Law and Biosciences Blog. *Litigation Watch: California's Drug Pricing Transparency Bill SB-17*. Retrieved from <https://law.stanford.edu/2018/01/06/litigation-watch-californias-drug-pricing-transparency-bill-sb-17/>.

All of the mandated reporting must be posted by the DOI on its website within 30 days of receiving the information in a manner that the public can identify the drug the reporting is regarding. Either the DOI or a third-party contractor must analyze and compile a report that delineates the effect of prescription drug costs on premiums. The data should be de-identified as to not reveal specific insurers in the report. This report is to be delivered to the relevant committees in the General Assembly starting in December 1, 2019. The DOI is to adopt rules, with assistance from other relevant agencies, to implement this legislation.

If a manufacturer violates the notification mandate or the required reporting to the DOI, the DOI can report the violations to the Colorado Board of Pharmacy. The board can discipline any licensee or registrant that has violated the aforementioned mandates. This disciplinary action can include a fine of at least \$1,000 per day for each day the manufacturer does not comply with the mandate.

Reasons to Support

The advanced notice could inform and aid purchasers. The notice could also provide assistance in scaling back potential WAC price increases, which tend to increase the prices down the line in the supply chain. Proponents claim that the notifications and reports could provide insight to policymakers in order to identify strategies to ensure the continued access to life-saving and life-improving pharmaceutical products at prices that are beneficial to consumers and manufacturers. Furthermore, the public notice could create a public relations backlash or shame that the companies would respond to by not increasing the WACs as often or as dramatically. Legislation such as this is considered to be a way for policymakers and the public to vent their frustrations with and continue to shine the spotlight on the pricing practices of the industry. If this bill was to pass, proponents believe it would signal to the industry that they do not have power over the legislation that travels through state legislatures.

Reasons to Oppose

Some assert that the WAC transparency that is mandated by the bill is not effective as it is mandating transparency of something that is already transparent. A drug's WAC is already publicly available from manufacturers or services that track prices. Furthermore, the mandate notifying purchasers of increases in WAC is not useful as it is not the list price of the drug. Therefore, there could be an increase in the WAC but the PBMs or carriers may not pay more than they did previously. Additionally, supporters claim that the advanced notice of the purchasers could help them push back against price increases but others claim that it is unknown what additional leverage the purchasers would have beyond the normal negotiating tactics they utilize to get receive rebates. The bill could have negative consequences. The advanced notice could allow wholesalers and distributors to buy up supplies of the drug at the lower price, and then after the price increase, sell the product for a large profit. Additionally, economic studies have consistently demonstrated that advanced price notice of this kind facilitates greater industry coordination.¹¹ Industry coordination can lead to higher prices as the manufacturers can create a market average and not have low-lying outliers that sell the product at a lower price.

Trade associations, PhRMA and Biotechnology Innovation Organization (BIO), have filed legal action in most of the states where similar bills have passed the legislature. If this legislation is passed, a lawsuit is to be expected. The cost of this action could require both monetary resources and staffing to defend the law in court.

Some may say that this transparency reporting mandate would require additional resources for manufacturers.

¹¹ Werden, G. (2004). Economic Evidence on the Existence of Collusion: Reconciling Antitrust Law with Oligopoly Theory. *Antitrust Law Journal*, 71(3), 719-800. Retrieved from <http://www.jstor.org/stable/40843604>

About this Document

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. For more information about this summary or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.