California Legislature Turns Focus on High Drug Pricing

Last month, we reviewed how the California Assembly is trying to understand cost drivers of healthcare overall. As California has the highest retail drug spending with prescription drug expenditures outpacing overall healthcare spending, high drug pricing has become a specific concern for the Legislature.[1] For the past few years, the Legislature has used bills[2] (like SB 17 (2017)), resolutions (like SJR 29 (2015)), and informational hearings to better understand and control high drug pricing.

For example, the Assembly Health Committee ("Committee") began a series of hearings to understand prescription drug pricing. On October 31, 2016, the Committee held the first hearing, "Understanding the Pharmaceutical Supply Chain: What is Driving Up the Cost of Drugs?". On February 14, 2017, the Committee held its second hearing, "Impact of Rising Drug Costs on Public and Private Payers." Additionally, on March 20, 2017, the Senate Committee on Business, Professions, and Economic Development held an informational hearing, "Pharmacy Benefits Managers 101," that examined, in part, the impact of pharmacy benefit managers on drug pricing. This month, we will be focusing on the latter two hearings.

Impact of Rising Drug Costs on Public and Private Payers

At this Assembly Health Committee hearing, various stakeholders testified on how increased drug pricing has negatively affected them. The speakers included public payers, like the Department of Health Care Services (Medi-Cal), California Public Employees' Retirement System (CalPERS), Department of General Services (DGS), and Los Angeles County

Department of Health, and private payers, like hospitals, Kaiser Permanente, large employer groups, small businesses, and health plans.

Higher Drug Costs Burden Payers

Nick Louizos of the California Association of Health Plans described the increased drug pricing as “inexplicable,” citing lower pricing in other countries. Following suit, Ambrose Carrejo, PharmD, of Kaiser Permanente called drug price increases “unexplainable” and “unsustainable,” noting these increases are not associated with innovation or additional value.

For example, the Department of General Services (DGS) saw its drug pricing increase more than 20%, with 25 of its drugs accounting for about 50% of total drug expenditures, while CalPERS saw its top 10 drugs account for 20% of all total pharmacy spending. Additionally, Medi-Cal has set aside $1.3 billion dollars just for Hepatitis C drugs and saw one drug increase by 49,000% from $0.05 to $23 a pill. Finally, Kaiser Permanente noted that Nitropress, a drug battling congestive heart failure and high blood pressure, increased 212% from $257.80 to $805.61, and Isuprel, a drug treating asthma and bronchitis, increased 525% from $215.46 to $1,346.62.

However, Kristin Manzolillo of Pfizer, Inc. responded that discounts and rebates for drugs are substantial and rising sharply, such that the net annual growth in drug price is only 2.8% for branded products. She argued that the prices some of the payers presented to the Committee are not contracted or actual prices paid but published average wholesale prices.

Whatever the actual increase in drug pricing may be, the Assembly Committee on Health identified “expensive specialty

drugs, monopoly pricing of old drugs, and an aging population" as possible trends that drive drug costs.[3]. Carrejo agreed that lack of competition is a reason for increased drug costs, while Louizos noted that unit price, not utilization, is a driving factor for increased drug costs.

Current Strategies Payers Implement to Reduce Drug Expenditures

Currently, DGS utilizes bulk purchasing to obtain volume discounts by contracting for more state departments to increase purchasing power and encouraging utilization of the same drugs to assist in bulk purchasing. To assist in these strategies, DGS formed the California Pharmaceutical Collaborative to coordinate these strategies with different state, local, and other governmental entities. Similarly, Kaiser Permanente and CalPERS try to use its market power to obtain greater drug discounts. Additionally, DGS directly contracts with drug manufacturers for greater discounts. On the other hand, CalPERs is working with pharmacy benefit managers (PBMs) to lower net cost of prescriptions. Finally, health plans and Kaiser Permanente devise prescription drug formularies such that more generic drugs are prescribed. If a prescription drug is similar in efficacy and safety, the health plans seek the less costly option.

What Should California Do?

To counter high drug pricing, Louizos recommended that the state of California should not restrict health plans from providing utilization management in terms of step therapy and prior authorization. By allowing health plans to encourage the use of lower priced but equally efficacious drugs first through step therapy and prior authorization, health plans can lower prescription drug expenditures.

Additionally, Louizos recommended that the state should do more to regulate drug manufacturers. One proposal that many

speakers, including Louizos, Yedidia, and Carrejo, endorsed is requiring transparency from drug manufacturers. Louizos noted that while drug copays are capped by state law, drug prices as set by drug manufacturers are not capped. In addition, while hospitals and health plans must release medical loss ratios, drug manufacturers are not required to be transparent with their pricing. Mario Yedidia of UNITE HERE International Union, echoed that transparency statutes are part of all other "legs" of the healthcare system except for the prescription drug sector.

Finally, a number of speakers, including Carrejo and John Jones, who represents PBMs from the Pharmaceutical Care Management Association, pushed for increased competition in the generic drug market so that more generic drugs can break the monopoly of brand name drugs. Mark Herbert of the Small Business Majority also testified that small businesses support proposals that would make it "illegal for a drug company to pay another company that makes generic drugs to delay the release of a generic drug."

Pharmacy Benefits Managers 101

At the Assembly Health Committee hearing, Amy Gutierrez, Chief Pharmacy Officer of Los Angeles County Department of Health Services, recommended that the state should adopt measures to regulate PBMs. A few weeks later, the Senate Committee on Business, Professions, and Economic Development held a hearing on Pharmacy Benefit Managers ("PBMs"), a "key player in the prescription-drug supply chain."[4]

PBMs Are Contributing to High Drug Prices

The background paper for this hearing noted that there is a "dearth of major players"[5] in the pharmaceutical industry, and that entry of generics to increase competition is disincentivized by "patents, FDA approvals, and high capital

costs."[6] As expressed by those at the Assembly hearing, the lack of transparency in prescription drug pricing makes it hard to know if someone is getting "ripped off",[7] as the lack of competition drives drug pricing further. The background paper implies that PBMs may be exacerbating the issue of lack of transparency and competition. In addition to not being transparent in terms of how they negotiate rebates and discounts with drug manufacturers, three major PBMs now control 75% of the market.[8]

David Balto, a former antitrust attorney for the Department of Justice and the Federal Trade Commission, argued that PBM profits are increasing with drug cost increases, and the lack of transparency by PBMs in how they price the drugs through discounts and rebates prevent payers from tackling high drug prices. As examples, Balto cited several federal cases against PBMs for "unjust enrichment through secret kickback schemes" in which "PBMs switch[ed] consumers to higher cost drugs, that often were less efficacious, in order to maximize rebates." He also cited Anthem's suit against Express Scripts for overcharges to prescription drugs to illustrate PBMs involvement in higher drug pricing.

What Should California Do?

Jon Roth of the California Pharmacists Association recommended that PBMs should be regulated by the California Board of Pharmacy, because they play a "crucial role in establishing the ultimate cost of prescription drug costs paid by consumers" and are "ubiquitous" in the drug supply chain, but have its business dealings "out of sight of regulators, consumers, and providers" and operate "in the shadows."

Balto agreed with Roth that a regulatory board should regulate PBMs and enforce future disclosure laws. In addition, he also echoed Roth's comment that PBMs are "one of the least regulated sectors of the health care system" and lack the elements of a competitive market due to lack of transparency

and conflicts of interest. As such, Balto argued, as did many of the panelists at the Assembly hearing, that transparency is essential to properly inform payers and keep PBMs accountable. He noted that states like New Jersey and Texas, which contracted with PBMs to provide increased transparency, saw decreased prices for their state employee health plans, while other large plans obtained greater cost savings when PBMs are required to disclose.

Conclusion

As the speakers from both hearings noted, the pharmaceutical industry and its players do not promote a prescription drug market with healthy competition. The hearings identified the lack of competition and transparency as major and solvable problems contributing to high drug pricing. Given the lack of competition and the dearth of transparency provisions, the passage of SB 17 (2017) is a great first step in promoting greater transparency from players of the drug supply chain. However, it is only the start to tackling the ever-increasing drug costs in California.

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[1] Assembly Committee on Health, Background Paper for Informational Hearing, Impact on Rising Drug Costs on Public and Private Payers at 9 (Feb. 14, 2017) (hereinafter "Payer Background"), http://ahea.assembly.ca.gov/sites/ahea.assembly.ca.gov/files/2%20Final%20background%20paper%20Drug%20II%20Feb%2014%202017.pdf.

[2] The Source has covered some of the drug pricing bills in length. For example, SB 17 is covered in part here and extensively here. Additionally, AB 265 is covered in part

here.

[3] Payer Background at 1, 9.

[4] Senate Committee on Business, Professions and Economic Development, Background Paper for Oversight Hearing, Pharmacy Benefit Managers 101 at 1 (Mar. 20, 2017) (hereinafter "PBM Background"), http://sbp.senate.ca.gov/sites/sbp.senate.ca.gov/files/PBM%20Background%20paper.pdf.

[5] *Id.* at 7.

[6] *Id.* at 8.

[7] *Id.* at 5.

[8] *Id.* at 6, 7.