

Governor Brown Signs Groundbreaking Drug Price Transparency Bill

What does the California Drug Transparency Bill (S.B. 17) Actually Do?

On Monday, October 9, Governor Jerry Brown [signed](#) S.B. 17, the California Drug Transparency Bill into law. Brown and the bill's supporters said the new California law should prompt action in other states and could be used by Congress as a blueprint to help rein in rising drug costs. The Mercury News [called the bill](#) "the nation's most comprehensive law aimed at shining a light on prescription drug prices." The law becomes effective on Jan 1, 2018 and seeks to: 1) promote transparency in pharmaceutical pricing|2) enhance understanding about pharmaceutical pricing trends|and 3) assist the state and other payers in management of pharmaceutical drug costs.[\[1\]](#) In short, the bill seeks to make drug prices more transparent and allow insurers to negotiate more effectively for lower drug prices.

To accomplish these aims, S.B. 17 requires additional reporting from health plans and pharmaceutical manufacturers.[\[2\]](#) Health plans must submit a report to the Department of Managed Health Care (DMHC) or Department of Insurance (DOI) with the 25 most frequently prescribed drugs, the 25 most costly drugs by total annual spending, and the 25 drugs with the highest increase in total spending.[\[3\]](#) In addition, large group plans must specify what portion of the premiums are attributable to prescription drugs overall (i.e., it is not restricted to only the top 25 most costly drugs). They must compare any increase in premiums due to prescription costs with increases due to other components of the health care premium (e.g. hospital inpatient, hospital outpatient,

and physician services). Manufacturers of a drug with a price[\[4\]](#) of more than \$40 must notify purchasers before increasing the price of the drug more than 16%.[\[5\]](#) Manufacturers must also submit reports about any new pharmaceutical with a price that exceeds the threshold of a specialty drug under Medicare Part D,[\[6\]](#) but that reporting is limited to information that is publically available.[\[7\]](#)

Will S.B. 17 restrict drug prices?

Unlike in Maryland, where the legislature recently [passed a law](#)[\[8\]](#) that allows the state's attorney general to step in if a drug's price increases more than 50 percent in a single year and assess a fine for price gouging,[\[9\]](#) the new CA law only requires drug manufacturers to report drug increases before they occur. Last fall, California voters rejected [a ballot initiative](#) that would have capped what state agencies paid for prescription drugs. In addition, Pharmaceutical Research and Manufacturers of America (PhRMA), the national trade group representing the pharmaceutical industry, [strongly opposed](#) the bill. The California legislature may not have been able to pass a bill that caps price increases, but will a law that only requires disclosures have any meaningful effect on drug prices?

According to [a report](#) by America's Health Insurance Plans, drug costs account for approximately 22 percent of every premium dollar, and are now the largest percentage of premium dollars, more than physician, inpatient, and outpatient hospital services. In addition, a [report](#) by Henry Waxman and colleagues found that while prescription drug use increased due to increased insurance coverage and an aging population, about a third of the rise in drug spending from 2010 to 2014 was due to either price increases or a shift toward higher-price drugs. Insurers have little incentive to negotiate to reduce drug prices because they can pass on most of the cost increases on to plan sponsors and beneficiaries.[\[10\]](#) The additional transparency from S.B. 17 may give plan sponsors

and insurers more negotiating power with the possibility of additional legislative action, perhaps price setting legislation, if lawmakers are unhappy with the behavior of pharmaceutical companies. Ed Hernandez, one of the sponsors of S.B. 17, acknowledges that the measure is unlikely to work on its own to curb rising drug prices, but sees it as [part of a wave of state and national efforts](#) to control drug prices.

Why just price increases? Won't drug manufacturers just price their drugs higher initially so avoid increasing prices?

The traditional view, that manufacturers release a branded product on the market at a premium price that remains until the drug faces generic competition, is outdated. Most drugs have substantially increased in price since their release. A [study](#) by the American Association of Retired Persons (AARP) found that between 2014 and 2015, retail prices for 268 brand-name prescription drugs widely used by older 130 times the rate of general inflation, and that 90% of brand-name drugs doubled their price in ten years. S.B. 17 only requires manufacturers to report drugs that increase more than 16% over *two years*, so manufacturers could limit their price increases to avoid reporting, but it would be at a rate approximately half of that found in the AARP study. A price increase of 16% over two years, however, means that the price of the drug could double over 12 years and not be subject to S.B. 17.

In reality, many drug manufacturers release their drugs at lower initial prices to capture market share, and then increase their prices in lock-step with their competitors. Competition has been unable to contain prices for brand-name drugs, even when multiple treatment options for a disease exist. For example, prices for drugs that treat Rheumatoid Arthritis have [increased more than 40%](#) in the last three years even though multiple companies released new drugs targeting different immune proteins. As noted above, bills that restrict price increases should mitigate the ability of drug companies to substantially increase prices in lock-step. S.B. 17,

however, only requires manufacturers to report price increases in advance.

Will S.B. 17 have an impact?

While the reporting requirements of S.B. 17 may give insurers and policy makers more information, the bill neglects to acknowledge the purchasing power of pharmacy benefit managers (PBMs). PBMs administer prescription drug programs for insurers and seek to secure lower drug costs by negotiating with drug manufacturers. PBMs negotiate rebates and discounts with manufacturers based on formularies. Manufacturers usually offer large rebates in exchange for placing their drug on a preferred tier in a formulary because the preferred status greatly increases the number of patients taking the drug. PBMs often share a portion of the rebate with insurers. In addition, because the size of the rebate typically depends on the drug price, the PBM has an incentive to negotiate higher drug prices with commensurately larger rebates. A [study by Visante](#) on behalf of Pharmaceutical Care Management Association (PCMA), the trade group representing PBMs, found no correlation between the increasing prices that drugmakers set on the top 200 brand drugs and the rebates that they negotiate with PBMs on those products. As a result, the wholesale average cost (that S.B. 17 would require the manufacturers to report has little correlation with the prices actually paid by most purchasers. For instance, to get around the reporting requirements of S.B. 17, manufacturers could decrease the rebates for some drugs, effectively increasing the net price above the 16% threshold. They could then increase the price (and rebates) for other drugs in their portfolio up to the 16%. This strategy would be most effective for large pharma companies with a diverse portfolio. The reporting required by S.B. 17 of *insurance plans* may help with this limitation because they will report net prices to the insurance plan (after receiving their portion of any rebates).

Furthermore, the negotiations between PBMs and manufacturers

usually reflect all of the drugs sold by that manufacturer. For example, a manufacturer might offer a substantial rebate for its blockbuster new drug in exchange for placement on a premier tier of a formulary (and perhaps a “fail-first” clause). They might then negotiate lower rebates on their other drugs sold to the same PBM for inclusion on that formulary. As a result, examining drug prices in isolation does not reflect the true nature of the market forces at play. Focusing only on the top 25 most expensive drugs or the price increases of an individual drug is unlikely to meaningfully reduce drug expenditures as a whole, as manufacturers can make up losses on one drug by lowering rebates on several others.

Conclusion

Drug prices are a primary concern to both the public and policy makers. A Kaiser Family Foundation [poll](#) found that 92% of Americans believe that the government should do something to address drug prices. The need for action is clear. In the last year, over [20% of Americans](#) did not fill a prescription because of cost. Because S.B. 17 is now a law, both the public and lawmakers will have much more insight into prescription drug pricing and expenditures. S.B. 17’s swift passage through both houses of the California legislature reflects both the desire of lawmakers to address the issue and the lack of any attempt to regulate prices directly. Nonetheless, its passage marks an important first step toward regulation of the industry. Because the bill only requires reporting (not an actual reduction in prices) and neglects key factors in the industry (i.e. WAC prices are not actual prices paid and PBMs couple negotiation on drug prices with manufacturers), its impact will likely be limited.

[\[1\]](#) S.B. 17 Section 127686

[\[2\]](#) In addition to the reporting discussed here, the bill also

requires DMHC and DOI to compile the reported information into a report for the public and legislators. The bill also requires pharmaceutical manufacturers to submit quarterly reports to the Office of Statewide Health Planning and Development (OSHPD) with increases they reported to purchasers and OSHPD to publish that information on their website.

[\[3\]](#) S.B. 17 Section 1

[\[4\]](#) Specifically, a Wholesale Average Price (WAC) of more than \$40 for a course of treatment.

[\[5\]](#) The percent increase is calculated cumulatively and includes any price increases that occurred within the previous two calendar years prior to the current year. The details of this calculation prevent companies from continuously making small increases in the price of the drug to avoid notifying purchasers.

[\[6\]](#) For 2017, CMS has set a cost-threshold of [\\$670 per month](#) to identify specialty drugs.

[\[7\]](#) S.B. 17 127681 (c)

[\[8\]](#) Maryland H.B.0631 Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition

[\[9\]](#) A group of generic manufacturers filed suit claiming the law was an “unconstitutional overreach” that will create market instability. U.S. District Judge Marvin Garbis allowed the lawsuit to proceed but [declined to issue an injunction against the law](#).

[\[10\]](#) The public will have access to 2 sets of information. First, the DMHC and DOI will issue annual reports that “demonstrate the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health insurers.” Second, the Office of Statewide Health Planning and

Development (OSHPD) will publish quarterly reports from pharmaceutical manufacturers about price increases and release of specialty drugs.