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## SENATE COMMITTEE ON HEALTH

Senator Ed Hernandez, O.D., Chair

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**BILL NO:** SB 1010  
**AUTHOR:** Hernandez  
**VERSION:** March 30, 2016  
**HEARING DATE:** April 13, 2016  
**CONSULTANT:** Melanie Moreno

**SUBJECT:** Health care: prescription drug costs

**SUMMARY:** Requires health plans and insurers that report rate information through the existing large and small group rate review process to also report specified information related to prescription drug pricing to Department of Managed Health Care (DMHC) and California Department of Insurance (CDI). Requires DMHC and CDI to compile specified reported information into a consumer-friendly report that demonstrates the overall impact of drug costs on health care premiums. Requires drug manufacturers to notify specified state purchasers, health plans, and health insurers, in writing at least 60 days prior to the planned effective date, if it is increasing the wholesale acquisition cost of a prescription drug by more than 10% during any 12-month period or if it intends to introduce to market a prescription drug that has a wholesale acquisition cost (WAC) of \$10,000 or more annually or per course of treatment. Requires drug manufacturers, within 30 days of notification of a price increase or of the introduction to market of a prescription drug that has a WAC of \$10,000 or more annually or per course of treatment, to provide specified information to purchasers, including a justification for the pricing.

**Existing law:**

- 1) Establishes the DMHC to regulate health care service plans (health plans) and the CDI to regulate insurers, including health insurers.
- 2) Requires health care service plans and health insurers to file specified rate information with DMHC or CDI, as applicable, for health care service plan contracts or health insurance policies in the individual or small group markets and for health care service plan contracts and health insurance policies in the large group market.
- 3) Requires, for large group health plan contracts and health insurance policies, plans and insurers to file with DMHC or CDI the weighted average rate increase for all large group benefit designs during the 12-month period ending January 1 of the following calendar year, and to also disclose specified information for the aggregate rate information for the large group market.
- 4) Requires health plans and health insurers, for the small group and individual markets, to file with DMHC and CDI, at least 60 days prior to implementing any rate change, specified rate information so that the departments can review the information for unreasonable rate increases.
- 5) Requires DMHC and CDI to accept and post to their Internet Web sites any public comment on a rate increase submitted to the departments during the 60-day period.
- 6) Under federal law, requires drug manufacturers to obtain approval of new drugs from the federal Food and Drug Administration (FDA).

- 7) Establishes the Sherman Law, administered by Department of Public Health (DPH), which, among other things, regulates the packaging, labeling, and advertising of drugs and medical devices in California.
- 8) Prohibits, in the Sherman Law, the sale, delivery, or giving away of any new drug or new device unless it is either:
  - a) A new drug, and a new drug application has been approved for it by the FDA, pursuant to federal law, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the FDA; or
  - b) A new drug or new device for which DPH has approved a new drug or device application, and has not withdrawn, terminated, or suspended that approval.
- 9) Requires DPH to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

**This bill:****Reporting of drug prices by health plans and insurers**

- 1) Requires health plans and insurers that report rate information through the existing large and small group rate review process to also report to DMHC and CDI, on a date no later than it reports the rate information, the information in a) through c) below for or all covered prescription drugs, including generic drugs, brand name drugs, specialty drugs, and prescription drugs provided in an outpatient setting or sold in a retail setting:
  - a) The 25 most frequently prescribed drugs and the average wholesale price (AWP) for each drug;
  - b) The 25 most costly drugs by total plan spending and the AWP for each drug; and,
  - c) The 25 drugs with the highest year-over-year increase and the AWP for each drug.
- 2) Requires DMHC and CDI to compile the reported information into a consumer-friendly report that demonstrates the overall impact of drug costs on health care premiums. Requires the data in the report to be aggregated and not reveal information specific to individual health care service plans. Requires DMHC and CDI to publish the report on its Internet Web site by January 1 of each year.
- 3) Requires DMHC and CDI to include the published report as part of the public meeting required under the existing large group rate review law.
- 4) Requires DMHC and CDI, except for the report required under 2) above, to keep confidential all of the information provided, and exempts that information from disclosure under the California Public Records Act.
- 5) Requires health plans and insurers, as part of reporting for large group rate review, to disclose the following information for covered prescription drugs, including generic drugs, brand name drugs excluding specialty drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use all of the following:

- a) The percentage of the premium attributable to prescription drug costs for the prior year for each category of prescription drugs;
- b) The year-over-year increase in the percentage of the premium attributable to each category of prescription drugs;
- c) The year-over-year increase in per member, per month costs for drug prices compared to other components of the health care premium;
- d) The specialty tier formulary list; and,
- e) The percentage of the premium attributable to prescription drugs administered in a doctor's office that are part of the medical benefit as separate from the pharmacy benefit, if available.

**Reporting of price increases and expensive pricing by drug manufacturers:**

- 6) Requires drug manufacturers of a branded prescription drug, or of a generic prescription drug with a price of \$100 or more per 30-day supply, to notify each state purchaser, health care service plan, or health insurer if it is increasing the wholesale acquisition cost of a prescription drug by more than 10% during any 12-month period or if it intends to introduce to market a prescription drug that has a WAC of \$10,000 or more annually or per course of treatment.
- 7) Requires the notice to be provided in writing at least 60 days prior to the planned effective date of the increase, and a copy of the notice to be provided concurrently to the Chairs of the Senate Committee on Appropriations, the Senate Committee on Budget and Fiscal Review, the Assembly Committee on Appropriations, and the Assembly Committee on Budget.
- 8) Specifies that a "state purchaser," for purposes of this bill includes, but is not limited to, the California Public Employees' Retirement System, the Department of Health Care Services (DHCS), the Department of General Services, and the California Department of Corrections and Rehabilitation (CDCR), or entity acting on behalf of a state purchaser.
- 9) Requires drug manufacturers, within 30 days of notification of a price increase, or of the introduction to market of a prescription drug that has a WAC of \$10,000 or more annually or per course of treatment, to report all of the following information to each state purchaser, health plan, or health insurer:
  - a) A justification for the proposed increase in the price of the drug, including all information and supporting documentation as to why the increase is justified.
  - b) The total dollar amount of public funding received by the manufacturer for the development and marketing, including, but not limited to, state and federal tax credits, grants, and all other public subsidies;
  - c) The expected marketing budget for the drug;
  - d) The date the drug was purchased if it was not developed by the manufacturer; and,
  - e) A schedule of past price increases for the drug.
- 10) Requires a fine of \$1,000 per day for every day after the 30-day notification period to be levied on manufacturers for failure to report the information in 9) above.
- 11) Requires the Legislature to conduct an annual public hearing regarding the price increases and information reported under 6) and 9) above. Requires the hearing to provide for public

discussion of the reasons for the price increases, emerging trends, decreases in drug prices, and the impact on health care affordability and premiums.

- 12) Prohibits this bill from restricting the legal ability of a drug manufacturer to change prices as permitted under federal law.

**FISCAL EFFECT:** This bill has not been analyzed by a fiscal committee.

**COMMENTS:**

- 1) *Author's statement.* According to the author, the introduction of new and innovative drugs is vital to our health care system, but these often high-priced treatments come with a multitude of challenges. Drugs priced in excess of \$10,000 are becoming common-place with little transparency for these astronomical price tags. This high-priced trend is a costly burden for patients, state programs, employers, and other payers, making it crucial that we understand what's behind the exploding prices. The public and policymakers need greater insight that will allow us to identify strategies to ensure prices do not threaten access to life-saving treatments. Additionally, data suggests that publically accessible price information in other sectors of the health care market encourage providers to offer more competitive pricing and thereby reduce excess health spending. Transparency-focused policies, like those implemented by the Affordable Care Act (ACA), have led to rules requiring hospitals in California to provide information on pricing for common surgeries, health plans to submit detailed data regarding premium changes, and doctors to report more information to the federal government. But, drug makers have been granted an exception to this forward-thinking trend. SB 1010 will bring prescription drugs in line with the rest of the health care sector by shedding light on those drugs that are having the greatest impact on our health care dollar. This change is absolutely necessary in an environment where more than 900 drugs are sporting price-tags at or above \$10,000 and new drugs with record-breaking prices are being released to address diseases that impact millions, including hundreds of thousands of patients in public programs like Medi-Cal.
- 2) *Health care costs.* Health care accounts for more than 17% of the U.S. Gross Domestic Product (\$3 trillion, or \$9,523 per person) and health care costs continue to consume significantly large percentages of federal, state and personal budgets. Health care continues to grow at higher rates than inflation. In 2013, the U.S. spent far more on health care than other high-income countries. Higher spending is due to multiple factors including greater use of medical technology and higher health care prices, not necessarily more frequent doctor visits or hospital admissions.
- 3) *Drug costs.* A study published in Health Affairs in December 2015 found that drug spending is growing faster than other health care spending in the U.S. – increasing 12.2% between 2013 and 2014. A Kaiser Family Foundation analysis of data from the Centers for Medicare and Medicaid Services and Truven Health Analytics shows that while drugs account for 10% of U.S. health spending, it represents 19% of the cost of employer insurance benefits. Some speculate that this disparity exists because the \$3 trillion in U.S. health spending is a broad catchall with includes hospital care, physician services, drugs, research, administrative costs, public health activities, and long-term care. Additionally, some of the people served by Medicare and Medicaid (whose spending is counted in the national totals) require many services not typically used by those covered by employer health plans. According to an analysis by the CEO of the Kaiser Family Foundation, even that 19% figure is understated because while it includes prescriptions that patients fill at pharmacies, it does not include

many of the expensive drugs administered in physicians' offices or hospitals. In Medicare, for example, retail prescription drugs represent 13% of overall spending while drugs administered mainly by physicians add an additional 6%.

- 4) *Drug pricing.* Federal regulations prohibit the U.S. government from setting the price of pharmaceuticals, and patents on drugs, in effect, prohibit competition, at least initially. Countries without these restrictions generally buy drugs for a fraction of the U.S. price. Pharmaceutical companies argue that high drug prices are justified because of the enormous cost and risk associated with bringing a drug to market and that payment for current drugs fund future innovation. Developing a new drug costs an average of \$1.2 billion and takes 10 to 15 years. When a new drug provides a cure for a disease, as opposed to only treating symptoms, drug companies claim that a high upfront cost is mitigated by not having to treat symptoms indefinitely. However, critics point to numerous examples of drug companies charging high prices for drugs with only marginal improvements over cheaper alternatives, or astounding increases in pricing for drugs that have been on the market for years.
- 5) *Price Benchmarks.* Knowing how much a drug costs is difficult; there are many different prices for each drug and different ways of expressing those prices. In the US, the two most common ways of stating drug prices are the WAC and average wholesale price (AWP). Neither one, though, is the actual price paid by a payer, nor are they what their names imply. Rather, they're standardized ways of expressing a price, thus allowing comparisons to be made from one drug to another. AWP is a benchmark that has been used for over 40 years for pricing and reimbursement of prescription drugs for both government and private payers. Initially, the AWP was intended to represent the average price that wholesalers used to sell medications to providers, such as physicians, pharmacies, and other customers. However, the AWP is not a true representation of actual market prices for either generic or brand drug products. AWP has often been compared to the "list price" or "sticker price," meaning it is an elevated drug price that is rarely what is actually paid. AWP is not a government-regulated figure, does not include buyer volume discounts or rebates often involved in prescription drug sales. As such, the AWP, while used throughout the industry, is a controversial pricing benchmark.

The WAC price of a drug on the market, as originally announced by the company is also rarely the price paid by a payer. The actual price paid by any one payer is proprietary information, complicating discussions of value and cost to consumers. Drug companies negotiate with payers – Medicare, Medicaid, insurers, and pharmacy benefit plans – to set an initial gross sales price. Drug manufacturers pay rebates back to government entities, creating a difference between gross sales for a drug and net sales. The rebates are not publicly available, and vary highly among payers and for different drugs. Estimates put them between 2% for innovative new drugs all the way to 60% for drugs that have several competitors or generics on the market.

Federal law requires manufacturers to provide rebates to the Centers for Medicare and Medicaid Services and state Medicaid agencies. The program requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to offset the overall cost of prescription drugs under the Medicaid program. According to DHCS, drug manufacturers are required to pay a Medi-Cal rebate for all outpatient drugs that

are dispensed and paid for by the Medi-Cal program. In addition, some manufacturers have agreed to pay supplemental Medi-Cal rebates above the standard rebate. Federal law requires rebates for prescriptions offered through the AIDS Drug Assistance Program (ADAP), in part because of the high cost of HIV/AIDS medications. According to the Kaiser Family Foundation, drug manufacturer rebates account for 40% of the annual ADAP budget.

- 6) *Impact on state finances.* Medi-Cal provides health care coverage for nearly one-third of Californians. Combined with CalPERS, ADAP, state hospitals, and corrections, taxpayer liability for increasing drug costs is significant. According to a December 2015 report published by the U.S. Senate Committee on Finance, Medi-Cal's fee-for-service system alone spent nearly \$25 million treating roughly 340 patients with Sovaldi and Harvoni in 2014. However, Medi-Cal fee-for-service is only a fraction of the Medi-Cal population. Private health plans invoiced the state an additional \$387.5 million for Sovaldi and Harvoni treatments for Medi-Cal managed care enrollees between July 2014 and November 2015 (for 3,624 patients) according to DHCS. Additionally, as a direct result of Sovaldi and Harvoni pricing, the 2015-16 California state budget allocated \$228 million just for high cost drugs to DHCS and CDCR. In December 2015, it was reported that CalPERS spent \$438 million on specialty drugs, an increase of 32% from the previous year. This represents one quarter of the total drug costs paid by CalPERS, while only 1% of the prescriptions filled.
- 7) *Support.* California Labor Federation, AFL-CIO (CLF), the sponsor of this bill, states that the drug manufacturer disclosure required under this bill gives purchasers advance notice of increases, along with additional information to discern between reasonable price increases and predatory pricing. CLF states that pharmaceutical companies produce lifesaving medications and it is critical that they are able to conduct research to make ground-breaking discoveries, however, not all price increases are related to R&D costs, nor are they based on effectiveness of the drug. CLF states that purchasers can use this information to better negotiate for discounts on drugs, or to decide that an unjustified price increase is grounds for refusing to purchase a drug.

SEIU California writes in support that because the state, taxpayers, and individuals pay significantly, at the individual and aggregate levels, this matters to all of us. SEIU states that the high-cost of specialty drugs creates a burden on the state budget, as Medi-Cal, CalPERS and other public programs struggle to cover the costs. CalPERS has reported that specialty drug spending increased 32% last year to \$438 million annually and Governor Brown's 2015 budget set aside supplemental funding of \$228 million to pay for a limited number of people who are served by public programs to receive Harvoni and Sovaldi. SEIU contends that when drugs are so expensive that it begins to make such a significant impact on our state budget, the pricing of these drugs also begins to raise ethical concerns and questions about how purchasers are making decisions related to how many sick people can or should get access to life-saving drugs. The California Alliance for Retired Americans (CARA) states that prescription drugs make up 19% of benefit costs in job-based coverage. However, that figure only captures drugs paid for through the pharmacy benefit—drugs administered in inpatient settings, like costly chemotherapy drugs, are paid for through medical benefits, and account for an even greater percentage of premiums. CARA writes that California can help purchasers and consumers better understand pharmaceutical pricing and give them the tools to fight back against price-gouging. Consumers Union writes that regulators and other reviewers need as much information as possible to determine whether a change proposed to health insurance rates is fair or not and this bill puts more tools into regulators' toolkits to

protect consumers in the marketplace and makes strides towards empowering consumers to be more informed participants in the marketplace.

Health Access California (HAC) writes that congressional investigations have found astronomical increases in drug prices, even for drugs that have been used for millennia. For some conditions, such as multiple sclerosis, the drugs used to manage the condition increase in price with every new drug entering the market—price competition to increase prices, not lower them. HAC states that this bill is a modest but important step forward in providing transparency on prescription drug costs. The National Multiple Sclerosis Society – CA Action Network writes that in addressing the costs of prescription drugs, this bill is a good starting point because it can be an important tool to help educate consumers about their health related expenses. American Association of Retired Persons (AARP) states that at a time when more and more high-cost drugs are entering the market, consumers, including many people over age 50, would benefit from a system that discloses important information about the pricing of these drugs. AARP believes that increased transparency in the marketplace will empower consumers and could provide much-needed clarity and a better understanding of the pharmaceutical industry’s pricing methods. The California School Employees Association states that they are often told that prescription drug costs are not the problem, and this bill will allow them to assess whether or not that is true and is an important and necessary step in understanding the costs of prescription drugs and how much of a cost driver they are. AIDS Healthcare Foundation writes that because their patient population is dependent on drugs regardless of the price, they are committed to solutions that ensure greater transparency in drug pricing that will lead to prices that can withstand public scrutiny.

- 8) *Opposition.* The Generic Pharmaceutical Association (GPhA) states that the generic industry’s business model is similar to a commodities market where prices, sometimes at pennies a dose, fluctuate up and down quickly and that generics provide so many savings because they operate in this hyper-competitive marketplace. GPhA asserts that a brand manufacturer patents a drug and sets the price but in the generic marketplace multiple manufacturers directly compete with each other and regularly adjust prices to best react to market conditions such as changes in supply costs, ingredient shortages, large orders from wholesalers, and other factors. The California Life Sciences Association (CLSA) writes that the information required of biopharmaceutical companies, health plans, and insurers would create a highly inaccurate picture of how medicines affect overall healthcare costs, and that this bill treats medication costs as solely expenditures, not an investment in more efficient care and better health for patients. CLSA asserts that this bill ignores all the benefits to patients, the healthcare system, and the economy that the life science sector provides, as well as the benefits to payers and pharmacy benefit managers from oftentimes significantly reduced, negotiated prices. CLSA further states that the bill’s requirement of advance notices prior to certain drugs being marketed, being accompanied by a “justification” with “supporting documentation” and an “expected marketing budget,” appears to violate FDA restrictions against preapproval marketing or promotion of investigational drugs, because the law and FDA’s subsequent guidance only clearly allow for the exchange of scientific information and preclude any form of “commercialization” prior to a medicine’s approval for commercial distribution. The reporting requirements as established in the bill are extraordinarily broad and would potentially apply to many medicines for which the impact on premiums of a price increase over the threshold of ten percent would be essentially de minimis and would reflect an imperceptible change in the total cost of care. The Pharmaceutical Research and Manufacturers of America (PhRMA) writes that while the information reported by the third party payers is in the aggregate and protected from

disclosure by creating specific exceptions to the California Public Records Act (PRA), the data required to be submitted to the state by the pharmaceutical industry includes sensitive proprietary information for specific products that would not enjoy the same PRA disclosure protections provided to the payers – presenting both proprietary and federal antitrust issues. PhRMA further states that the requirement for a 60-day advance notice does not appear to be protected information and could thus be anti-competitive, as disclosure of planned pricing changes could have unintended consequences and is generally viewed as extremely disruptive to the competitive marketplace.

**SUPPORT AND OPPOSITION:**

- Support:** California Labor Federation, AFL-CIO (sponsor)  
AARP  
AIDS Healthcare Foundation  
Blue Shield of California  
California Alliance for Retired Americans  
California Association of Health Plans  
California Medical Association  
California Nurses Association  
California Optometric Association  
California School Employees Association  
Consumers Union  
Health Access California  
Kaiser Permanente  
LIUNA Locals 777 & 792  
National Multiple Sclerosis Society – CA Action Network  
SEIU California  
Unite Here
- Oppose:** California Life Sciences Association  
Generic Pharmaceutical Association  
Pharmaceutical Research and Manufacturers of America

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