

Prescription Drug Cost Transparency Legislation in the States

As the use and cost of prescription drugs continues to rise, it is critically important to understand the investment behind the development and marketing of such drugs in order for policymakers to ensure continued access to affordable medications.

Legislation now introduced in 5 states (CA [AB 463](#), MA [SB 1048](#), NC [HB 839](#), OR [HB 3486](#), PA [HB 1042](#)) requires certain drug makers to report costs related to development, production, distribution and administrative costs for the prescription drugs offered to patients in the state. Another bill (TX [HB 4002](#)) seeks to study this issue using data over the interim and bring recommendations to the 2017 legislative session.

- These bills seeks to allow consumers and policymakers to have essential information about the underlying costs of prescription drugs and develop solutions to enable continued access to affordable medications.

This legislation seeks to bring information to the public that we desperately need to include in any solutions dealing with high cost drugs.

- Today, policymakers and the public have no data on how prescription drugs are priced – we hear from the pharmaceutical industry that they are setting their prices to recoup research and development costs and to invest in new therapies. However, it is estimated that pharmaceutical companies spend less than 20% of their revenue on research and development of new medications.
- Any information on current drug pricing and cost structures required extensive review of hundreds of SEC filings to determine overall spending by these drug makers (and estimates of what is occurring in private firms) – yet, this information is not readily or easily available for policymakers or the public. We think it’s time to change that.

Over the last several decades, the use of prescription drugs has increased significantly and now accounts for approximately 14% of total claims paid by health insurers.¹

Specialty drugs—which are generally understood to be drugs that are structurally complex and often require special handling or delivery mechanisms—are priced much higher than traditional drugs. While these drugs have been ground breaking in the treatment of cancer, rheumatoid arthritis, multiple sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed tens of thousands of dollars a year.

- In 2014, U.S. spending on prescription drugs totaled nearly \$379 billion— a third of which was spent on specialty drugs.²
- The treatment regimen for some of the most expensive specialty drugs can cost \$750,000 per year.³
- The problem facing policymakers is urgent – growth in specialty drug prices significantly

¹ PricewaterhouseCoopers, “The Factors Fueling Rising Healthcare costs”.

² IMS Institute for Healthcare Informatics. Medicines Use and Spending Shifts: A Review of the Uses of Medicines in the U.S. in 2014; April 2015.

³ Brian Schilling. “Purchasing High Performance: Specialty Drugs Poised to Skyrocket but Many Employers Have Yet To Take Notice.” *The Commonwealth Fund*; April 2012.

outpaced growth in wages and the consumer price index between 2011 and 2013.⁴

- A recent analysis published in *Health Affairs* modeled the impact of a hypothetical specialty drug that cost \$100,000 per treated patient would increase total health care costs by \$250 for every 0.25 percent of the population using the drug.⁵ Under this model, such a specialty drug used by just 5 percent of the population would lead to an almost 15 percent increase in premiums.
- In many states, other providers are required to report cost data so policymakers and the public to provide a better understanding of costs (i.e. hospitals costs, payments to physicians, etc). However, no such data is known about prescription drugs. It is time to change that.

Many of these bills requires that certain information be submitted only on certain drugs (i.e. those costing more than \$10,000 per year or treatment), limiting the reporting to the highest cost drugs.

- This streamlines the focus to the high cost drugs and avoids unnecessary administrative burden on many drug makers who produce lower cost drugs.

This bill does not require proprietary payment rates that drug makers may pay clinical trial practitioners, nor does it require detailed trade secret information.

- These bills simply ask for information that is part of the overall drug development process, none of which will produce competitive harm to any drug maker.
- This bill asks for aggregate costs that the manufacturer tracks related to the development, production, and distribution of these drugs.
- Recent amendments made to the California bill (AB 463) allow the state agency (OSHPD) to retain any information filed that it believes is confidential or proprietary and would do competitive harm if disclosed.

⁴ Specialty Drug Hyperinflation: Escalating Costs for the Healthcare System. The Campaign for Sustainable Rx Pricing. April 2015.

⁵ The Impact of Specialty Pharmaceuticals As Drivers of Health Care Costs. *Health Affairs*, 33, no. 10 (2014): 1714-1720. Available at: <http://content.healthaffairs.org/content/33/10/1714.full.pdf>.

Why Assertions of “Sensitivity of Information” Do Not, and Should Not, Undermine the Efforts to Provide Important Public Benefits through AB 463

PhRMA objections to AB 463 include the suggestion that some of the information should not be collected by the State because of its proprietary, confidential, or sensitive nature. The PhRMA letter indicates that:

- ✓ "The 'total costs of clinical trials' is a **closely guarded, proprietary** number. Every pharmaceutical company handles their clinical trials differently, and for a variety of reasons the company does not want this data to fall into the hands of their competitors."
- ✓ "The bill seeks total costs information regarding 'other costs to acquire the drug, including...purchase of patents, licensing or acquisition of any corporate entity owning any rights to the drug...If a company purchased another business, the terms and conditions of the transaction are often kept **confidential** by contract."
- ✓ "Medicare and Medicaid, two the nation's largest drug purchasers do not seek such **sensitive information.**"

For at least three reasons, these arguments do not, and should not, undermine the efforts to provide important public benefits through AB 463.

(1) The factual assertions made above are not correct and some mix concepts in an attempt to bring non-confidential information into the realm of confidential information.

- For example, the terms and conditions of transactions may be publicly reported in SEC filings. In addition, the sensitivity of particular strategies a pharmaceutical company may use in their clinical trials does not mean that the total costs of such trials is a sensitive number. In fact, the PhRMA letter makes the point that "[w]here is the utility of documenting one company spending \$500 million to perform the research and development of a cancer therapy and a different company spending \$750 million on a pulmonary medicine."
- We believe there is tremendous utility in this knowledge to the State of California and its citizens who are bearing the staggering costs associated with such therapies, but no competitive utility (and therefore harm) by having one pharmaceutical company know such aggregated figures about other pharmaceutical companies.

(2) Although some of the information requested may be sensitive, it is not a trade secret and legislatures have the power to, and routinely do, require disclosure, publication, and even the direct sharing of such information when it is in the public interest. This is often done with the knowledge that it will have a direct impact on marketplace transactions. This is part of the balancing of competing interests that legislatures routinely engage in, sometimes determining that the greatest public good will come from the disclosure of certain information.

- That is not to indicate that legislatures do, or should, broadly disseminate sensitive information without good reason. Where the information is less sensitive (e.g., because sought at a generalized level that does not implicate trade secret concerns) and/or its disclosure is more beneficial to the public (e.g., to inform policy solutions to high and escalating prices of prescription drugs), legislatures can and have required the dissemination of information.
- The public interest at issue due to the significant impact of high cost pharmaceuticals on the State and its citizens is compelling and are not outweighed by the issues raised in the PhRMA letter. See, for example, *Beeman v. Anthem Prescription Management LLC*, 315 P.3d 71, 93 (Cal. 2013) (noting that the statute at issue and others, simply require disclosure of factual information in order to inform private or public decisionmaking in the economic or political marketplace).
- We acknowledge that the drug manufacturers would prefer not to make these disclosures. That is not sufficient to decide the issue, however, and the legislature should determine that the information must be made available in order to promote informed choice in the free market and in the development of sound public policy.

(3) The information being collected does not qualify as a trade secret according to accepted legal standards.

- For example, California, like many states has adopted the Uniform Trade Secrets Act (See California Civil Code § 3426 - § 3426.11). This provides protection for "trade secrets," which are defined under the act as:
 - "information, including a formula, pattern, compilation, program, device, method, technique, or process, that:*
 - (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and*
 - (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.*
- Even assuming that some of the information may be of sensitive nature, it still must *"derive independent economic value..from not being generally known to the public or to other person who can obtain economic value from its disclosure or use."*
- Simply not wanting to release the information is not sufficient. "[T]he confidential information must give the holder an economic *advantage* and threaten a *competitive injury*—business information whose release harms the holder only because the information is embarrassing or reveals weaknesses does not qualify for trade secret protection." *Cook Inc. v. Boston Scientific Corp.*, 260 F.R.D. 244 (S.D. Ind. 2001). There is no reason to believe that publication of highly aggregated information, such as total costs of clinical trials or other total costs of research and development efforts for a drug would meet this standard.

ASSEMBLY BILL

No. 463

Introduced by Assembly Member Chiu

February 23, 2015

An act to add Chapter 9 (commencing with Section 127675) to Part 2 of Division 107 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 463, as introduced, Chiu. Pharmaceutical Cost Transparency Act of 2015.

Existing law establishes the Office of Statewide Health Planning and Development, which is vested with all the duties, powers, responsibilities, and jurisdiction of the State Department of Public Health relating to health planning and research development.

This bill would require each manufacturer of a prescription drug, made available in California, that has a wholesale acquisition cost of \$10,000 or more annually or per course of treatment to file a report, no later than May 1 of each year, with the Office of Statewide Health Planning and Development on the costs for each qualifying drug, as specified. The bill would require the office to issue a report annually to the Legislature outlining the information submitted pursuant to this act, and the office would be required to post the report on its Internet Web site. The bill would also require the office to convene an advisory workgroup, as provided, to develop the reporting form required by this act.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Chapter 9 (commencing with Section 127675)
2 is added to Part 2 of Division 107 of the Health and Safety Code,
3 to read:

4
5 CHAPTER 9. PHARMACEUTICAL COST TRANSPARENCY ACT OF
6 2015
7

8 127675. The Legislature finds and declares all of the following:

9 (a) It is the intent of the Legislature to make information
10 available to the public about the cost of ultra-high-priced
11 pharmaceuticals, in order to make pharmaceutical pricing as
12 transparent as the pricing in other sectors of the health care
13 industry.

14 (b) To fulfill this goal, the Legislature finds that there should
15 be annual cost reporting on the most expensive drugs that would
16 be of use by policymakers, government agencies, and others to
17 understand costs for these important products.

18 127676. (a) Each manufacturer of a prescription drug, made
19 available in California, that has a wholesale acquisition cost (WAC)
20 of ten thousand dollars (\$10,000) or more annually or per course
21 of treatment, shall file a report pursuant to this section on the costs
22 for each qualifying drug.

23 (b) The report shall include all of the following for each drug:

24 (1) The total costs for the production of the drug, including all
25 of the following:

26 (A) The total research and development costs paid by the
27 manufacturer, and separately, the total research and development
28 costs paid by any predecessor in the development of the drug.

29 (B) The total costs of clinical trials and other regulatory costs
30 paid by the manufacturer, and separately, the total costs of clinical
31 trials and other regulatory costs paid by any predecessor in the
32 development of the drug.

33 (C) The total costs for materials, manufacturing, and
34 administration attributable to the drug.

35 (D) The total costs paid by any entity other than the
36 manufacturer or predecessor for research and development,
37 including any amount from federal, state, or other governmental
38 programs or any form of subsidies, grants, or other support.

1 (E) Any other costs to acquire the drug, including costs for the
2 purchase of patents, licensing or acquisition of any corporate entity
3 owning any rights to the drug while in development, or all of these.

4 (F) The total marketing and advertising costs for the promotion
5 of the drug directly to consumers, including, but not limited to,
6 costs associated with direct to consumer coupons and amount
7 redeemed, total marketing and advertising costs for promotion of
8 the drug directly or indirectly to prescribers, and any other
9 advertising for the drug.

10 (2) A cumulative annual history of average wholesale price
11 (AWP) and WAC increases for the drug (expressed as percentages),
12 including the months each increase in each category, AWP and
13 WAC, took effect.

14 (3) The total profit attributable to the drug as represented in
15 total dollars and represented as a percentage of the total company
16 profits that were derived from the sale of the drug.

17 (4) The total amount of financial assistance the manufacturer
18 has provided through patient prescription assistance programs, if
19 available.

20 (c) All of the information in subdivision (b) shall be itemized
21 and documented by the manufacturer, and audited by a fully
22 independent third-party auditor prior to filing.

23 (d) The information required by this section shall be filed
24 annually with the Office of Statewide Health Planning and
25 Development on a form prescribed by the office and shall be
26 submitted no later than May 1 of each year.

27 (e) (1) Notwithstanding Section 10231.5 of the Government
28 Code, the Office of Statewide Health Planning and Development
29 shall issue a report annually to the Legislature outlining the
30 information submitted pursuant to this section, and the office shall
31 post the report publicly on its Internet Web site.

32 (2) A report submitted to the Legislature pursuant to this
33 subdivision shall be submitted in compliance with Section 9795
34 of the Government Code.

35 (f) The Office of Statewide Health Planning and Development
36 shall convene an advisory workgroup to develop the form required
37 by this section. The workgroup shall include, but is not limited to,
38 representatives from the pharmaceutical industry, health care

- 1 service plans and insurers, pharmacy benefit managers,
- 2 governmental agencies, consumer advocates, and physicians.

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