AMENDED IN ASSEMBLY JANUARY 4, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

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 amended, Chiu. Pharmaceutical Cost Transparency Act of ~~2015.~~ *2016.*

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~~ *the bill and* 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.~~ *bill. The bill would require the office to maintain the confidentiality of any information submitted by a prescription drug*

manufacturer pursuant to those provisions that the director of the office deems to be confidential and proprietary.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

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

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

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

CHAPTER 9. PHARMACEUTICAL COST TRANSPARENCY ACT OF ~~2015~~ *2016*

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

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

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

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

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

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

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

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

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

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

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

~~(F)~~

(2) The total marketing and advertising costs for the promotion of the drug directly to consumers, including, but not limited to, costs associated with ~~direct to consumer~~ *direct-to-consumer* coupons and amount redeemed, total marketing and advertising costs for promotion of the drug directly or indirectly to prescribers, and any other advertising for the drug.

~~(2)~~

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

~~(3)~~

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

~~(4)~~

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

(6) The total costs of drugs or research projects that failed to succeed through the process to market approval.

(c) *(1)* All of the information in subdivision (b) shall be itemized and documented by the manufacturer, and audited by a fully independent third-party auditor prior to filing.

(2) The information reported by a manufacturer pursuant to paragraph (1) of subdivision (b) shall be limited to the time period from five years prior to the filing date of an Investigational New Drug application with the United States Food and Drug Administration to the approval date of the New Drug Application by the United States Food and Drug Administration. This paragraph shall not prohibit a manufacturer from separately providing that information outside of that time period.

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

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

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

(f) The ~~Office of Statewide Health Planning and Development~~ *office* shall convene an advisory workgroup to develop the form required by this section. The workgroup shall include, but is not limited to, representatives from the pharmaceutical industry, health care service plans and insurers, pharmacy benefit managers, governmental agencies, consumer advocates, and physicians.

(g) The office shall maintain the confidentiality of any information submitted pursuant to this section that the director deems to be confidential, proprietary information of the prescription drug manufacturer, the disclosure of which would cause the manufacturer competitive harm. This confidential proprietary information shall not be made public by the office and is exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). This paragraph shall not limit the disclosure of information that is not attributed to a specific manufacturer or that is released in aggregate.

SEC. 2. The Legislature finds and declares that Section 1 of this act, which adds Section 127676 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to protect proprietary, confidential information from prescription drug manufacturers and to protect the integrity of the competitive market, it is necessary that this act limit the public's right of access to that information.

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