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:

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

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 or acquisition of any corporate entity owning any rights to the drug while in development, or all of these.

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

(c) 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.

(d) The information required by this section shall be filed annually with the Office of Statewide Health Planning and Development 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 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 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.

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