AMENDED IN SENATE JANUARY 6, 2014

AMENDED IN SENATE APRIL 23, 2013

AMENDED IN SENATE APRIL 15, 2013

SENATE BILL No. 747

Introduced by Senator DeSaulnier

February 22, 2013

An act to add Article 6 (commencing with Section 108670) to Chapter 5 of Part 3 of Division 104 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 747, as amended, DeSaulnier. Public ~~Health Impact Report~~ *health impact assessments*.

Existing law requires the State Department of Public Health to regulate various consumer products, including food and drugs, for the protection of the people of the state.

This bill, known as the Public Health Epidemic Prevention Act of ~~2013,~~ *2014,* would ~~require~~ *authorize* the department to ~~require~~ *submit a written request to* the manufacturer or a group of manufacturers of a contributing product, as defined, to ~~create, for approval of the department, a public health impact report (PHIR) containing~~ *submit a written response to the department's determination that the product is a contributing product. The bill would require the written response to contain* specified information, including a ~~list~~ *risk assessment* of adverse public health impacts and a mitigation plan for those impacts. ~~The bill would require the manufacturer to mitigate the fiscal impacts on the state public health system over a reasonable period of time. The bill would authorize the department to enforce the PHIR and would authorize~~

~~the department to restrict sales of the product in the state if the PHIR is insufficient or if the manufacturer is not complying with the terms of the PHIR.~~ The bill would authorize the department to charge the manufacturer of the *contributing* product *an amount not exceeding $20,000* for the reasonable costs of ~~reviewing, approving, and enforcing the PHIR requirements~~ *reviewing the risk assessment and mitigation document*.

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. The Legislature finds and declares all of the following:

(a) Public health for the people of the state is now, and in the future, a matter of statewide concern.

(b) The health and well-being of all people is a critical element in supporting a healthy and prosperous California, including economic sustainability, increasing workforce participation and productivity, and slowing the ongoing rise of medical care expenditures.

(c) California and its residents face a growing burden of largely preventable chronic illness, including heart disease, stroke, obesity, and diabetes.

(d) It is the intent of the Legislature to find ways to develop and maintain public health, prevent negative public health risks, provide the people of the state with protection from products sold in the state that pose significant negative health risks, and develop mitigation strategies.

(e) It is the intent of the Legislature to take immediate steps to identify products sold in the state for consumer consumption that pose a critical public health risk and coordinate any actions necessary to prevent or mitigate those risks.

(f) It is the intent of the Legislature to regulate products sold in the state for consumer consumption that pose significant public health risks and mitigate their use in order to prevent chronic illness and improve public health.

SEC. 2. Article 6 (commencing with Section 108670) is added to Chapter 5 of Part 3 of Division 104 of the Health and Safety Code, to read:

Article 6. Public Health Impact Assessments

108670. This article shall be known, and may be cited, as the Public Health Epidemic Prevention Act of ~~2013~~ *2014*.

108671. For the purposes of this article, the following definitions shall apply:

(a) "Contributing product" means a manufactured product intended for consumer consumption in this state for which the department has credible evidence that use of the product significantly contributes to a public health epidemic and that meets both of the following criteria:

(1) The public health epidemic to which the product contributes is one recognized by the federal Centers for Disease Control and Prevention, the United States Department of Health and Human Services, the Surgeon General, or the United States Food and Drug Administration.

(2) The adverse impact on public health from use of the product in this state would have a fiscal impact of fifty million dollars ($50,000,000) or more annually on the state public health system, including, but not limited to, public hospitals and overall Medi-Cal expenditures.

(b) "Credible evidence" means peer-reviewed research, data, and studies currently available to the department.

(c) "Department" means the State Department of Public Health.

(d) "Manufacturer" means the manufacturer ~~that created the public health impact report or, if the public health impact report was created by a group of the largest manufacturers, every manufacturer that participated in the study and submitted the report to the department~~ *whose name appears on the label of a product that is identified by the department as a contributing product*.

108672. ~~(a)~~ If the department determines that a product is a contributing product, then the department ~~shall require~~ *may submit a written request to* the contributing product's largest manufacturers, representing 80 percent of the costs identified in *paragraph (2) of* subdivision (a) *of Section 108671* and that do business in the state, to ~~create a public health impact report (PHIR). The PHIR shall be submitted to the department for approval. As appropriate, the department may grant permission for the contributing product's largest manufacturers to participate in one study and submit one PHIR to the department for approval.~~ *submit*

a written response to the department's determination that the product is a contributing product. The written response shall include, but not be limited to, all of the following:

(1) A written risk assessment analysis that identifies the public health impacts resulting from the sale of the product in this state.

(b) A list of mitigation strategies sufficient to reasonably reduce adverse public health impacts identified in the risk assessment.

~~(b) The PHIR shall include all of the following:~~

~~(1) A list of adverse public health impacts that cannot be avoided if the product is sold in the state.~~

~~(2) The benefits, costs, and alternatives to the contributing product.~~

~~(3) Alternatives available, if any.~~

~~(4) A mitigation plan sufficient to reasonably reduce the adverse public health impacts identified in paragraph (1), to be implemented by the manufacturer.~~

~~(c) The manufacturer shall mitigate the adverse public health fiscal impacts on the state's health system over a reasonable period of time. The mitigation plan shall consider and prioritize the most cost-effective mitigation.~~

~~(d) In preparing the mitigation plan, manufacturers may create and fund an advisory committee to make recommendations.~~

~~(e) Prior to approval or rejection of the PHIR, the department shall report to the respective Senate and Assembly committees on health and budget. The department may take actions necessary to enforce the PHIR, including, but not limited to, requiring that the manufacturer establish a trust or place moneys in escrow sufficient to cover the estimated costs of implementation.~~

~~(f) If the department determines that the PHIR prepared by the manufacturer is insufficient or that the manufacturer is not complying with the terms of the PHIR, then the department may restrict the sale of the product in this state, as appropriate.~~

108673. The department ~~shall~~ *may* enact all regulations necessary to implement this article pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

108674. The department may charge the manufacturer of the *contributing* product *an amount not exceeding twenty thousand dollars ($20,000)* for the reasonable costs of ~~reviewing, approving, and enforcing the PHIR requirements~~ *reviewing the risk assessment*

and mitigation document submitted pursuant to Section 108672. Fees collected pursuant to this subdivision shall be placed in the Public Health Fund, which is hereby established in the State Treasury and which may be used by the department, upon appropriation by the Legislature, for the implementation of this article.

108675. Notwithstanding subdivision (c) of Section 25257.1, the requirements of this article shall not be interpreted to affect any authority of the Department of Toxic Substances Control pursuant to Article 14 (commencing with Section 25251) of Chapter 6.5 of Division 20.

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