

AMENDED IN ASSEMBLY APRIL 20, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1174

Introduced by Assembly Member Bonilla

February 27, 2015

An act to ~~amend Section 137 of~~ *add Sections 100240, 100241, 100242, and 100243* to the Health and Safety Code, relating to ~~public health~~: *health research*.

LEGISLATIVE COUNSEL'S DIGEST

AB 1174, as amended, Bonilla. ~~Women's health~~. *Health research: women's health*.

Existing law establishes the Inclusion of Women and Minorities in Clinical Research Act, which requires a grantee, as defined, in conducting or supporting a project of clinical research, as defined, to ensure that women of all ages, and members of minority groups, as defined, are included as subjects in the clinical research projects, except under prescribed circumstances. Existing law also requires state agencies to, and would declare legislative intent that the University of California include in specified progress reports, data on the extent to which state funds administered by state agencies and the University of California are used by grantees for research on diseases, disorders, and health conditions, that includes women and minorities in the research trials, and that studies diseases, disorders, and health conditions of particular concern to women and minorities. Existing law also states the legislative intent that research include, but not be limited to, specified diseases, disorders, and health conditions.

This bill would create the State Contingency Fund for Ancillary Costs and the Ancillary Costs Committee. The bill would authorize the fund

to receive private donations. The bill would require the committee to develop grant criteria once a to be determined amount is deposited into the fund. The bill would authorize the committee to award, on a competitive basis, grants to various organizations, to increase patient access to cancer clinical trials.

~~Existing law imposes various functions and duties on the State Department of Public Health with respect to the administration and oversight of various health programs and facilities relating to the prevention of disease and the promotion of health. The department is required to develop a coordinated state strategy for addressing the health-related needs of women, including implementation of goals and objectives for women’s health.~~

~~This bill would require the State Department of Public Health to report to the Assembly Committee on Health and the Senate Committee on Health the state strategy, goals established, and progress made toward achieving those goals on or before January 1, 2017, and biennially thereafter. The bill would make related changes.~~

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. *The Legislature finds and declares the following:*
- 2 (a) *Almost 50 percent of clinical trial studies do not finish in*
- 3 *time due to low patient participation, recruitment and navigation*
- 4 *difficulties, and other barriers for patients. Due to economic and*
- 5 *socioeconomic circumstances and lack of patient knowledge,*
- 6 *clinical oncology trial participation and retention are both very*
- 7 *low as they relate to eligible participants.*
- 8 (b) *Overall, only 3 percent of eligible cancer patients participate*
- 9 *in clinical trials and of those, only 5 percent of trial participants*
- 10 *are from racial or ethnic minority communities.*
- 11 (c) *One barrier that prevents patients from participating in*
- 12 *federal Food and Drug Administration clinical trials is finances.*
- 13 *Patients can’t bear the burden of the ancillary costs of*
- 14 *participating, such as airfare, lodging, rental cars, and fuel.*
- 15 SEC. 2. *Section 100240 is added to the Health and Safety Code,*
- 16 *to read:*
- 17 100240. *The Ancillary Costs Committee is hereby created to*
- 18 *be made up of private and public health stakeholders.*

1 SEC. 3. Section 100241 is added to the Health and Safety Code,
2 to read:

3 100241. (a) The State Contingency Fund for Ancillary Costs
4 is hereby created in the State Treasury to be made up of donations
5 from private entities. Moneys in the State Contingency Fund for
6 Ancillary Costs shall, upon appropriation by the Legislature to
7 the committee, be allocated by the committee as provided by
8 Section 100242.

9 (b) The board shall not use more than 10 percent of funds made
10 available for the grant program for administrative costs.

11 SEC. 4. Section 100242 is added to the Health and Safety Code,
12 to read:

13 100242. (a) Upon an unspecified amount of moneys being
14 donated to the fund, the committee shall establish a grant program
15 to determine grant parameters and criteria, and to make grant
16 awards.

17 (b) In order to increase patient access to clinical trials, the
18 committee may award grants from any funds that may be made
19 available pursuant to Section 100241, on a competitive basis, to
20 both of the following:

21 (1) Public and private research institutions and hospitals that
22 conduct cancer trials approved by the federal Food and Drug
23 Administration approved cancer clinical trials.

24 (2) A nonprofit organization described in Section 501(c)(3) of
25 the Internal Revenue Code of 1954 which is exempt from income
26 tax under Section 501(a) of that code that specializes in direct
27 patient support for improved clinical trial enrollment and retention.

28 (c) The funds awarded pursuant to subdivision (b) shall be used
29 for activities to increase patient access to clinical trials, including,
30 but not limited to:

31 (1) Payment of ancillary costs for patients and caregivers,
32 including, but not limited to:

33 (A) Airfare during the clinical trial.

34 (B) Lodging during the clinical trial.

35 (C) Rental cars during the clinical trial.

36 (D) Fuel during the clinical trial

37 (E) Meals during the clinical trial.

38 (F) Child care costs during the clinical trial.

39 (2) Patient navigator services or programs.

40 (3) Education and community outreach.

1 (4) Patient-friendly technical tools to assist patients in
2 identifying available clinical trials.

3 SEC. 5. Section 100243 is added to the Health and Safety Code,
4 to read:

5 100243. Grant recipients shall report to the committee to
6 ensure the appropriate use of the funds.

7 SECTION 1. ~~Section 137 of the Health and Safety Code is~~
8 ~~amended to read:~~

9 137. (a) ~~The State Department of Public Health shall develop~~
10 ~~a coordinated state strategy for addressing the health-related needs~~
11 ~~of women, including implementation of goals and objectives for~~
12 ~~maintaining and improving women’s health.~~

13 (b) ~~The approved programmatic costs associated with this~~
14 ~~strategy shall be the responsibility of the State Department of~~
15 ~~Public Health unless otherwise provided by law.~~

16 (e) (1) ~~The State Department of Public Health shall report to~~
17 ~~the Assembly Committee on Health and the Senate Committee on~~
18 ~~Health on the state strategy, goals established, and progress made~~
19 ~~toward achieving those goals. This report shall be submitted on or~~
20 ~~before January 1, 2017, and biennially thereafter.~~

21 (2) ~~Pursuant to Section 10231.5 of the Government Code, the~~
22 ~~requirement for submitting a report imposed under paragraph (1)~~
23 ~~is inoperative on January 1, 2021.~~