S-1310.1

SUBSTITUTE SENATE BILL 5388

State of Washington 68th Legislature 2023 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Rivers, Cleveland, Muzzall, Conway, Frame, Hasegawa, Keiser, Lovelett, Lovick, Pedersen, Rolfes, Saldaña, Valdez, and C. Wilson)

AN ACT Relating to improving diversity in clinical trials; and adding a new chapter to Title 69 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** (1) The legislature finds that controlled clinical trials provide a critical base of evidence for evaluating whether a medical product is effective before the product is approved for marketing. The food and drug administration has evaluated demographic profiles of people participating in clinical trials for approved drugs and found that some groups, especially ethnic and racial groups, are not always well represented in clinical trials. Diversity in clinical trials is necessary to effectively determine how race, gender, and age impacts how a person metabolizes a drug.

(2) Therefore, it is the policy of the state to:

(a) Improve the completeness and quality of data concerning diverse demographic groups that is collected, reported, and analyzed for the purposes of clinical trials of drugs and medical devices;

(b) Identify barriers to participation in clinical trials by persons who are members of demographic groups that are underrepresented in such trials and employ strategies recognized by the United States food and drug administration to encourage greater participation in clinical trials by such persons; and

(c) Make data concerning demographic groups that is collected, reported, and analyzed for the purposes of clinical trials more available and transparent.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

"Washington state review board" or "review board" means the Washington state institutional review board, established pursuant to 45 C.F.R. Part 46, which is the designated institutional review board for the department of social and health services, the department of health, the department of labor and industries, and other state agencies.

NEW SECTION. **Sec. 3.** (1) The Washington state review board must establish a diversity in clinical trials program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in clinical trials. In developing this program, the review board may:

(a) Review the most recent version of "Collection of Race and Ethnicity Data in Clinical Trials — Guidance for Industry and Food and Drug Administration Staff," published by the United States food and drug administration;

(b) Collaborate with medical facilities, health authorities, and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research relating to drugs or medical devices to assist such investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;

(c) Establish and maintain a website that:

(i) Provides information concerning methods recognized by the United States food and drug administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(ii) Contains links to websites maintained by medical facilities, health authorities, and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are

performing research relating to drugs or medical devices in this state;

(d) Apply for grants from any source including, without limitation, the federal government, to fund the diversity in clinical trials program; and

(e) Beginning July 1, 2024, and every even-numbered year thereafter, submit a report concerning the status and results of the diversity in clinical trials program to the health care committees of the legislature.

(2) Any state entity that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices must:

(a) Adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States food and drug administration to identify and recruit such persons to participate in those clinical trials;

(b) Provide information to trial participants in languages other than English; and

(c) Provide translation services or bilingual staff for trial screening.

(3) For the purposes of this section, demographic groups that are underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, and age.

NEW SECTION. **Sec. 4.** Sections 1 through 3 of this act constitute a new chapter in Title 69 RCW.

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