

Senate Bill No. 1364

CHAPTER 941

An act to amend Section 56.17 of the Civil Code, and to amend Section 124980 of, to amend and renumber Section 125005 of, and to add Section 124981 to, the Health and Safety Code, relating to health, and making an appropriation therefor.

[Approved by Governor September 29, 2000. Filed
with Secretary of State September 30, 2000.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1364, Johnston. Genetics: test disclosure.

Existing law, the Confidentiality of Medical Information Act, imposes prohibitions on the disclosure of the results of a test for a genetic characteristic contained in an applicant's or enrollee's medical records by a health care service plan.

This bill would specify, for those prohibitions, a definition for the term "genetic characteristic," that is the same as the definition contained in existing provisions regarding health care service plans.

Existing law requires the State Department of Health Services to recommend appropriate criteria and standards for licensing genetic counselors, and requires the department to consult with a group of medical experts representing medical professional organizations during the process of developing and recommending the criteria and standards.

This bill, instead, would require that standards for hereditary disorders programs established by the department include licensure of master level genetic counselors and doctoral level clinical geneticists. The bill would also require that counseling services for hereditary disorders be provided by a physician or other appropriately trained licensed health care professional.

The bill would prohibit any person from using the title of genetic counselor unless the person has applied for and obtained a license from the department. The bill would specify licensing requirements with regard to a genetic counselor.

Existing law authorizes the department to charge a fee for genetic disease testing of children and requires that all moneys collected be deposited in the Genetic Disease Testing Fund, a continuously appropriated special fund.

This bill would authorize the department to charge fees for licensing activities required under the bill and would require the fees collected to be deposited in the Genetic Disease Testing Fund. Because this bill would provide for new fees to be deposited into the

Genetic Disease Testing Fund, a continuously appropriated special fund, this bill would make an appropriation.

Appropriation: yes.

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

SECTION 1. Section 56.17 of the Civil Code is amended to read:

56.17. (a) This section shall apply to the disclosure of genetic test results contained in an applicant's or enrollee's medical records by a health care service plan.

(b) Any person who negligently discloses results of a test for a genetic characteristic to any third party in a manner that identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization as described in subdivision (g), shall be assessed a civil penalty in an amount not to exceed one thousand dollars (\$1,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(c) Any person who willfully discloses the results of a test for a genetic characteristic to any third party in a manner that identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization as described in subdivision (g), shall be assessed a civil penalty in an amount not less than one thousand dollars (\$1,000) and no more than five thousand dollars (\$5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(d) Any person who willfully or negligently discloses the results of a test for a genetic characteristic to a third party in a manner that identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization as described in subdivision (g), that results in economic, bodily, or emotional harm to the subject of the test, is guilty of a misdemeanor punishable by a fine not to exceed ten thousand dollars (\$10,000).

(e) In addition to the penalties listed in subdivisions (b) and (c), any person who commits any act described in subdivision (b) or (c) shall be liable to the subject for all actual damages, including damages for economic, bodily, or emotional harm which is proximately caused by the act.

(f) Each disclosure made in violation of this section is a separate and actionable offense.

(g) The applicant's "written authorization," as used in this section, shall satisfy the following requirements:

(1) Is written in plain language.

(2) Is dated and signed by the individual or a person authorized to act on behalf of the individual.



(3) Specifies the types of persons authorized to disclose information about the individual.

(4) Specifies the nature of the information authorized to be disclosed.

(5) States the name or functions of the persons or entities authorized to receive the information.

(6) Specifies the purposes for which the information is collected.

(7) Specifies the length of time the authorization shall remain valid.

(8) Advises the person signing the authorization of the right to receive a copy of the authorization. Written authorization is required for each separate disclosure of the test results.

(h) This section shall not apply to disclosures required by the Department of Health Services necessary to monitor compliance with Chapter 1 (commencing with Section 124975) of Part 5 of Division 106 of the Health and Safety Code, nor to disclosures required by the Department of Managed Care necessary to administer and enforce compliance with Section 1374.7 of the Health and Safety Code.

(i) For purposes of this section, “genetic characteristic” has the same meaning as that set forth in subdivision (d) of Section 1374.7 of the Health and Safety Code.

SEC. 2. Section 124980 of the Health and Safety Code is amended to read:

124980. The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety. Standards shall include licensure of master level genetic counselors and doctoral level clinical geneticists. Regulations adopted shall implement the principles established in this section. These principles shall include, but not be limited to, the following:

(a) The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.

(b) The incidence, severity, and treatment costs of each hereditary disorder and its perceived burden by the affected community should be considered and, where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders shall be consulted by the department.

(c) Information on the operation of all programs on hereditary disorders within the state, except for confidential information obtained from participants in the programs, shall be open and freely available to the public.

(d) Clinical testing procedures established for use in programs, facilities, and projects shall be accurate, provide maximum



information, and the testing procedures selected shall produce results that are subject to minimum misinterpretation.

(e) No test or tests may be performed on any minor over the objection of the minor's parents or guardian, nor may any tests be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders and is given reasonable opportunity to object to the testing.

(f) No testing, except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions.

(g) Pretest and posttest counseling services for hereditary disorders shall be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder. Genetic counseling shall be provided by a physician, a certified advanced practice nurse with a genetics specialty, or other appropriately trained licensed health care professional and shall be nondirective, shall emphasize informing the client, and shall not require restriction of childbearing.

(h) All participants in programs on hereditary disorders shall be protected from undue physical and mental harm, and except for initial screening for phenylketonuria (PKU) and other diseases that may be added to newborn screening programs, shall be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease shall be informed of the nature, and where possible the cost, of available therapies or maintenance programs, and shall be informed of the possible benefits and risks associated with these therapies and programs.

(i) All testing results and personal information generated from hereditary disorders programs shall be made available to an individual over 18 years of age, or to the individual's parent or guardian. If the individual is a minor or incompetent, all testing results that have positively determined the individual to either have, or be a carrier of, a hereditary disorder shall be given through a physician or other source of health care.

(j) All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released, provided that the individual is first fully informed of the scope of the information



requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available, except for data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to Subpart A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations entitled “Basic HHS Policy for Protection of Human Subjects,” the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

(k) An individual whose confidentiality has been breached as a result of any violation of the provisions of the Hereditary Disorders Act, as defined in subdivision (b) of Section 27, may recover compensatory damages and, in addition, may recover civil damages not to exceed ten thousand dollars (\$10,000), reasonable attorney’s fees, and the costs of litigation.

(l) “Genetic counseling” as used in this section shall not include communications that occur between patients and appropriately trained and competent licensed health care professionals, such as physicians, registered nurses, and physicians assistants who are operating within the scope of their license and qualifications as defined by their licensing authority.

SEC. 3. Section 124981 is added to the Health and Safety Code, to read:

124981. (a) No person shall use the title of genetic counselor unless the person has applied for and obtained a license from the department.

(b) The applicant for a genetic counselor license shall meet minimum qualifications that include but are not limited to all of the following:

(1) Has earned a master’s degree or above from a program specializing in or having substantial course content in genetics.

(2) Has demonstrated competence by an examination administered or approved by the department.

(c) The license shall be valid for three years unless at any time during that period it is revoked or suspended. The license may be renewed prior to the expiration of the three-year period.

(d) To qualify to renew the license, a licenseholder shall have completed 45 hours of continuing education units during the three-year license renewal period. At least 30 hours of the continuing education units shall be in genetics.

(e) The license fee for an original license and license renewal shall not exceed two hundred dollars (\$200).



SEC. 4. Section 125005 of the Health and Safety Code is amended and renumbered to read:

124996. (a) The Genetic Disease Testing Fund is continued in existence as a special fund in the State Treasury. The department may charge a fee for any activities carried out pursuant to the Hereditary Disorders Act, including licensing activities conducted pursuant to Section 124980. All moneys collected by the department under the act shall be deposited in the Genetic Disease Testing Fund, that is continuously appropriated to the department to carry out the purposes of the act.

(b) It is the intent of the Legislature that the program carried out pursuant to the act be fully supported from fees collected under the act.

(c) The director shall adopt regulations establishing the amount of fees for activities carried out pursuant to the act.

(d) The “Hereditary Disorders Act” or “act” referred to in this section is the act described in subdivision (b) of Section 27.

