

ACT 252

S.B. NO. 2763

A Bill for an Act Relating to Birth Defects.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Chapter 321, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

“PART . HAWAII BIRTH DEFECTS PROGRAM

§321- Definitions. As used in this part, unless the context requires otherwise:

“Adverse reproductive outcome” means a birth defect, stillbirth, infant death up to one year of age, or spontaneous or medical termination of pregnancy for a birth defect.

“Birth defect” means an abnormality of structure, function, or body metabolism present at birth that adversely affects a child’s health and development, results in a physical or mental disability, or is fatal.

“Institutional review board” means an institutional review board established in accordance with 7 Code of Federal Regulations 1c.107, 10 Code of Federal Regulations 745.107, 14 Code of Federal Regulations 1230.107, 15 Code of Federal Regulations 27.107, 16 Code of Federal Regulations 1028.107, 21 Code of Federal Regulations 56.107, 22 Code of Federal Regulations 225.107, 24 Code of Federal Regulations 60.107, 28 Code of Federal Regulations 46.107, 32 Code of Federal Regulations 219.107, 34 Code of Federal Regulations 97.107, 38 Code of Federal

Regulations 16.107, 40 Code of Federal Regulations 26.107, 45 Code of Federal Regulations 46.107, 45 Code of Federal Regulations 690.107, or 49 Code of Federal Regulations 11.107.

§321- Birth defects program. The department of health shall establish the statewide Hawaii birth defects program to:

- (1) Collect surveillance information on birth defects and other adverse reproductive outcomes;
- (2) Report the incidence, trends, and causes of birth defects and other adverse reproductive outcomes;
- (3) Report information for the development of prevention strategies to reduce the incidence of birth defects and other adverse reproductive outcomes; and
- (4) Develop strategies to improve the access of children with birth defects to health and early intervention services.

§321- Confidentiality of data. (a) The identity of, or any information which alone or in combination with other reasonably available information that may be used to identify, any person whose information is collected under this part shall be confidential.

(b) Statistical data and information that do not identify any person may be released.

§321- Rules. The department may adopt rules pursuant to chapter 91 as necessary for the Hawaii birth defects program.

§321- Requests for information. The department shall provide information about appropriate health and early intervention services to persons who request the information.

§321- Hawaii birth defects special fund. There is established within the state treasury the Hawaii birth defects special fund to be administered and expended by the department of health, into which shall be deposited fees remitted pursuant to section 572-5. Moneys in the special fund shall be used for the payment of the operating expenses of the Hawaii birth defects program.”

SECTION 2. Chapter 324, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

“PART . BIRTH DEFECTS STUDIES

§324- Definitions. As used in this part, unless the context requires otherwise:

“Adverse reproductive outcome” means a birth defect, stillbirth, infant death up to one year of age, or spontaneous or medical termination of pregnancy for a birth defect.

“Birth defect” means an abnormality of structure, function, or body metabolism present at birth that adversely affects a child’s health and development, results in a physical or mental disability, or is fatal.

“Institutional review board” means an institutional review board established in accordance with 7 Code of Federal Regulations 1c.107, 10 Code of Federal Regulations 745.107, 14 Code of Federal Regulations 1230.107, 15 Code of Federal Regulations 27.107, 16 Code of Federal Regulations 1028.107, 21 Code of Federal Regulations 56.107, 22 Code of Federal Regulations 225.107, 24 Code of Federal

Regulations 60.107, 28 Code of Federal Regulations 46.107, 32 Code of Federal Regulations 219.107, 34 Code of Federal Regulations 97.107, 38 Code of Federal Regulations 16.107, 40 Code of Federal Regulations 26.107, 45 Code of Federal Regulations 46.107, 45 Code of Federal Regulations 690.107, or 49 Code of Federal Regulations 11.107.

“Registry” means a collection of data organized so that the information can be processed and made available for research.

“Research” means a systematic investigation designed to develop or contribute to generalizable knowledge.

“Researcher” means a person who is conducting research which has been approved or declared exempt by an institutional review board.

§324- Information collection. (a) Health care facilities and health care providers shall make available to the Hawaii birth defects program information contained in health care records that pertain to birth defects or other adverse reproductive outcomes.

(b) Any person or public or private health care facility may provide information or other data or relevant material relating to individuals with birth defects or adverse reproductive outcomes to the Hawaii birth defects program for inclusion in the birth defects registry.

(c) This part shall not apply if the parent, guardian, or other person having custody or control of the child objects on the grounds that the collection of the information conflicts with their religious beliefs. The written objection shall be made a part of the child’s medical record.

(d) No liability of any kind or character for damages or other relief shall arise or be enforced against any person or organization by reason of having provided information or material to the Hawaii birth defects program.

§324- Use of collected information. (a) The information collected under this part shall be used by the department of health or researchers only for the purpose of advancing medical and public health research, medical education, or education of the public in the interest of reducing morbidity or mortality, and only as approved by an institutional review board.

(b) The identity of, or any information which alone or in combination with other reasonably available information that may be used to identify, any person whose condition or treatment has been studied under this part shall be confidential.

(c) If the Hawaii birth defects program or researchers intend to collect additional information directly from a patient or patient’s relative for research studies approved by an institutional review board, the researcher shall first obtain approval for the request from the patient’s attending physician. The use of the additional information obtained by researchers shall be governed by subsection (a).

§324- Penalty. Any person violating this part shall be guilty of a misdemeanor and fined not more than \$500.”

SECTION 3. Section 572-5, Hawaii Revised Statutes, is amended by amending subsections (a) and (b) to read as follows:

“(a) The department of health shall appoint, and at its pleasure remove, one or more suitable persons as agents authorized to grant marriage licenses under this chapter in each judicial circuit. The agents may issue licenses from any state facility when deemed necessary by the director. Any agent appointed under this subsection and receiving an application for a marriage license shall collect from the applicant for the license [~~\$50;~~ \$60, of which the agent, except those provided for in subsection (b), shall retain \$9 for the agent’s benefit and compensation and shall

remit ~~[\$41]~~ \$51 to the director of health. Upon the receipt of remittances under this subsection, the director of health shall deposit:

- (1) \$32 for each license issued to the credit of the general fund of the State;
- (2) \$4.50 for each license issued to the credit of the spouse and child abuse special account established under section 346-7.5; ~~[and]~~
- (3) \$4.50 for each license issued to the credit of the spouse and child abuse special account established under section 601-3.6[-]; and
- (4) \$10 for each license issued to the credit of the Hawaii birth defects special fund established under section 321-.

(b) The department may appoint, as regular employees under the civil service and classification laws, the number of suitable persons as agents authorized to grant marriage licenses for whom provision has been made in the general appropriation act. In the case of these agents, the full amount collected from applicants shall be remitted to the director of health. Upon the receipt of remittances under this subsection, the director of health shall deposit:

- (1) \$41 for each license issued to the credit of the general fund of the State~~{};{}]~~
- (2) \$4.50 for each license issued to the credit of the spouse and child abuse special account established under section 346-7.5~~{}; [and]~~
- (3) \$4.50 for each license issued to the credit of the spouse and child abuse special account established under section 601-3.6[-]; and
- (4) \$10 for each license issued to the credit of the Hawaii birth defects special fund established under 321-.

SECTION 4. There is appropriated out of the Hawaii birth defects special fund the sum of \$200,000, or so much thereof as may be necessary for fiscal year 2002-2003, to pay for the operating expenses of the Hawaii birth defects program established by this Act.

The sum appropriated shall be expended by the department of health for the purposes of this Act.

SECTION 5.¹ This Act shall take effect on July 1, 2002.

(Approved July 1, 2002.)

Note

- 1. No ramseyer clause.