CHAPTER 324
MEDICAL RESEARCH; MORBIDITY AND MORTALITY INFORMATION

Part I. Maternal and Perinatal Studies

Section

Part II. Mental Health and Intellectual Disability Studies

Part III. Cancer Studies

Part IV. Health Surveillance

Part V. Birth Defects Studies

Cross References

Child death review, see §§321-341 to 346, part XXVII.

"PART I. MATERNAL AND PERINATAL STUDIES

§324-1 Requests for information; sources of information protected. (a) Upon written request from the director of health, all providers of health care, social services, and county and state agencies shall provide information, reports, statements, memoranda, death and birth records, or other data or material relating to the condition and treatment of any person to the department of health or its designee, to be used in the course of any study for the purpose of reducing maternal morbidity or mortality.

(b) To the extent that this section conflicts with other state confidentiality and disclosure laws, this section shall prevail.

(c) The department of health may request information regarding the deceased that is stored in electronic format or in paper copies, or gathered through interviews, subject to certain restrictions, which include but are not limited to:

(1) Social, medical, and legal histories;
(2) Death and birth certificates;
(3) Law enforcement investigative data;
(4) Medical examiner or coroner investigative data;
(5) Parole and probation information and records;
(6) Information and records of social service agencies;
(7) Educational records;
(8) Medical records; and
(9) Interviews with hospital employees that shall be subject to approval from hospital management.

Furthermore, all requested disclosures shall comply with state and federal privacy statutes and regulations, including the Health Insurance Portability and Accountability Act, and the department of health shall not request records of any hospital review committee, peer review committee, or quality improvement review process. The department may enter into a memorandum of agreement with hospitals regarding requests for information to be used for maternal mortality reviews.

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 the information or material, or by reason of having released or published the findings, conclusions, and summaries of the research or study committees to advance medical research and medical education.

(d) Except as otherwise provided in this part, all maternal mortality review information acquired by the department during its review of maternal deaths pursuant to this part is confidential and shall only be disclosed as necessary to carry out the purposes of this part.

(e) No individual participating in the review of a maternal death shall be questioned in any civil or criminal proceeding regarding information presented in or opinions formed as a result of a panel meeting. Nothing in this subsection shall be construed to prevent a person from testifying to information obtained independently of the department's request for maternal mortality review information or the panel's review of the maternal death, or which is public information, or where disclosure is required by a court of law.

(f) Maternal mortality review information held by the department as a result of maternal mortality reviews conducted pursuant to this part shall not be subject to subpoena, discovery, or introduction into evidence in any civil or criminal proceeding, except that maternal mortality review information otherwise available from other sources shall not be immune from subpoena, discovery, or introduction into evidence through those sources solely because they were provided to the department as required by this part. [L 1963, c 109, §1; Supp, §48B-1; HRS §324-1; am L 1990, c 326, §13(1); am L 2016, c 203, §6]

" **§324-2 Identification of persons studied; restriction.** The department of health, or its designee, or any in-hospital staff committee shall use or publish this material only for the purpose of advancing medical research, medical education, or education of the public in the interest of reducing morbidity or mortality. In all events, the identity, or any group of facts which tends to lead to the identity, of any person whose condition or treatment has been studied shall be confidential and shall not be revealed under any circumstances. [L 1963, c 109, §2; Supp, §48B-2; HRS §324-2; am L 1990, c 326, §13(2); am L 2016, c 203, §7]

" **§324-3 Legal proceedings; information excluded from.** Any findings, conclusions, or summaries resulting from medical studies within the scope of this part shall not be used or made available in any legal proceeding. Any information set forth in section 324-1 provided to any research or study committee shall not be used or made available in any legal proceeding unless it is unobtainable from the original source. In such event, the judicial officer shall in camera inspect the committee's findings, conclusions, or summaries and make available factual

information contained therein. [L 1963, c 109, §3; Supp, §48B-3; HRS §324-3]

" **§324-4 Penalty.** Any person violating this part shall be guilty of a misdemeanor and fined not more than $500. [L 1963, c 109, §4; Supp, §48B-4; HRS §324-4]

Cross References

Classification of offense and authorized punishment, see §§701-107, 706-640, 663.

" **[§324-5] Multidisciplinary and multiagency reviews.** The department of health may conduct multidisciplinary and multiagency reviews of maternal deaths to reduce the incidence of preventable maternal deaths. [L 2016, c 203, pt of §5]

" **[§324-6] Maternal death review reports.** (a) The director of health shall submit an annual written report to the legislature no later than twenty days prior to the convening of each regular session on the status of reviews of maternal deaths conducted by the department. The annual report shall cover the calendar year immediately prior to the year in which the report is due and shall describe the total number of deaths of women while pregnant or within one year after a pregnancy in Hawaii, the causes of those deaths and whether the causes of death were pregnancy related, any maternal mortality review activities conducted by the department, trends in maternal deaths, and recommendations for system changes, including any proposed legislation.

(b) The director of health shall submit a copy of any other maternal death review report published by the department of health, detailing findings and recommendations resulting from such a review, to the legislature upon the report's publication. [L 2016, c 203, pt of §5]

"PART II. MENTAL HEALTH AND INTELLECTUAL DISABILITY STUDIES

Note

Part heading amended by L 2011, c 220, §1.

§324-11 Sources of information protected. Any person, public or private medical facility, or social or educational agency, may provide information, interviews, reports, statements, memoranda, or other data or relevant material

relating to individuals to the department of health to be used in the course of any study for the purpose of reducing morbidity or mortality resulting from mental illness or intellectual disability.

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 the information or material, or by reason of having released or published the findings, conclusions, and summaries of the research or study committees to advance medical research and medical education. [L 1964, c 13, §2; Supp, §48B-11; HRS §324-11; am L 2011, c 220, §12]

" **§324-12 Identification of persons studied; restriction.** The material shall be used or published only for the purpose of advancing medical research, medical education, or education of the public in the interest of reducing morbidity or mortality. The identity, or any group of facts which tends to lead to the identity, of any person whose condition or treatment has been studied shall be confidential and shall not be revealed in any reports or any other matter prepared, released, or published by the research or study committees under any circumstances. [L 1964, c 13, §3; Supp, §48B-12; HRS §324-12]

" **§324-13 Legal proceedings; information excluded from.** Any findings, conclusions, or summaries resulting from medical studies within the scope of this part shall not be used or made available in any legal proceeding. Any information provided to any research or study committee shall not be used or made available in any legal proceeding unless it is unobtainable from the original source. In such event, the judicial officer shall in chambers inspect the committee's findings, conclusions, or summaries and make available factual information contained therein. [L 1964, c 13, §4; Supp, §48B-13; HRS §324-13]

" **§324-14 Penalty.** Any person violating this part shall be guilty of a misdemeanor and fined not more than $500. [L 1964, c 13, §5; Supp, §48B-14; HRS §324-14]

Cross References

Classification of offense and authorized punishment, see §§701-107, 706-640, 663.

"PART III. CANCER STUDIES

§324-21 Sources of information protected. (a) Any person, public or private medical facility, or social or educational agency, may provide information, interviews, reports, statements, memoranda, biological specimens, or other data or relevant material relating to individuals with cancer or pre-cancerous conditions to the Hawaii Tumor Registry. This information may be used in the course of any cancer research study approved by the cancer commission of the Hawaii Medical Association and the appropriate federally authorized human subjects protection board.

(b) Hospitals, skilled nursing homes, intermediate care homes, free-standing radiation oncology facilities, and other treatment or pathology facilities shall submit a report of any person admitted with or diagnosed as having cancer to the Hawaii Tumor Registry or participating hospital registry according to a format approved by the cancer commission of the Hawaii Medical Association. Physicians who diagnose or treat a patient for cancer shall also submit a report to the Hawaii Tumor Registry or participating hospital registry unless the patient has previously been admitted or treated at a hospital, skilled nursing home, intermediate care home, or free-standing radiation oncology facility for that particular cancer. The Hawaii Tumor Registry staff or their representative or hospital-based registry staff may assist the hospitals, institutions, treatment or pathology facilities, and physician offices in the preparation of the reports.

(c) 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 the information or material, or by reason of having released or published the findings, conclusions, and summaries of the researchers to advance medical research and medical education. [L 1973, c 25, pt of §1; am L 1976, c 30, §1; am L 2000, c 17, §2; am L 2008, c 117, §3]

" **§324-22 Identity of persons studied and material, restrictions.** (a) The material collected under this part shall be used or published only for the purpose of advancing medical research, medical education, or education of the public in the interest of reducing morbidity or mortality; provided that the Hawaii Tumor Registry may reveal all relevant information to a patient's attending physician.

(b) The identity or any group of facts that tends to lead to the identity of any person whose condition or treatment has been studied shall be confidential and shall not be revealed in any report or any other matter prepared, released, or published. Researchers, however, may use the names of persons when

requesting additional information for research studies after being approved by the cancer commission of the Hawaii Medical Association and the appropriate federally authorized human subjects protection board.

(c) The use of additional information obtained by researchers shall also be governed by subsection (a) and, in addition, where the patient is still living and the information is to be obtained directly from the patient, the researcher shall first obtain the approval of the patient or the patient's immediate family, including a reciprocal beneficiary, in that order of priority. [L 1973, c 25, pt of §1; gen ch 1985; am L 1997, c 383, §41; am L 2008, c 117, §4]

" **§324-23 Legal proceedings; information excluded from.** Except as otherwise provided, findings, conclusions, or summaries resulting from medical studies within the scope of this part shall not be used or made available in any legal proceeding. Any information provided to any researcher or study committee shall not be used or made available in any legal proceeding unless it is unobtainable from the original source. In such event, the judicial officer shall in chambers inspect the findings, conclusions, or summaries and make available factual information contained therein. [L 1973, c 25, pt of §1]

" **§324-24 Penalty.** Any person violating this part shall be guilty of a violation. [L 1973, c 25, pt of §1; am L 1975, c 24, §9]

"PART IV. HEALTH SURVEILLANCE

§324-31 Identity of persons studied and material, restrictions. The identity, or any group of facts or any system of records which may lead to the identity, of any person whose condition or treatment has been studied shall be confidential and shall not be revealed in any report, release, or publication. The department of health may, however, use the names of persons when requesting additional information; provided that approval shall first be obtained from the individual, the individual's parents or guardian in the case of a minor, or the next of kin in the case of a deceased person; and provided that the identity or facts identifying the person shall not be released outside of the department of health. [L 1977, c 117, pt of §1]

Revision Note

Subsection designation deleted.

" **§324-32 Release of information.** (a) Consistent with section 324-31 and Public Law 93-380, the department of health may, if not otherwise prohibited by law release statistical records or information relating to the health surveillance program. The materials collected under this part shall only be used for the analysis of health, demographic, socio-economic, environmental and related factors for the evaluation of health problems, health programs, delivery and utilization of medical care, analysis and interpretation of public health trends, forecasting long and short range public health needs and for the determination of programs to meet such needs.

(b) The department of health may collect additional information requested by other public or private agencies and may release statistical information from the health surveillance program for research, educational or program purposes to the public or private agencies or individuals. [L 1977, c 117, pt of §1]

" **§324-33 Legal proceedings; information excluded from.** Findings, conclusions, or summaries pertaining to any individual resulting from studies within the scope of this part shall not be used against the individual or made available in any legal proceeding without the individual's consent. [L 1977, c 117, pt of §1]

" **§324-34 Penalty.** Any person violating this part shall be guilty of a misdemeanor. [L 1977, c 117, pt of §1]

"[PART V.] BIRTH DEFECTS STUDIES

[§324-41] 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. [L 2002, c 252, pt of §2]

" **[§324-42] Information collection.** (a) Health care facilities and health care providers shall make available to the [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 [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 [birth defects program]. [L 2002, c 252, pt of §2]

Cross References

Birth defects program, see §321-422.

" **§324-43 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 and health care providers in the interest of reducing morbidity or mortality or increasing physicians' knowledge of resources available for families of

persons with birth defects, and only as approved or exempted 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 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 primary care provider. If the patient's current physician is not known, the patient may be contacted directly using a method approved by an institutional review board. The use of the additional information obtained by researchers shall be governed by subsection (a). [L 2002, c 252, pt of §2; am L 2016, c 20, §1]

" **[§324-44] Penalty.** Any person violating this part shall be guilty of a misdemeanor and fined not more than $500. [L 2002, c 252, pt of §2]