AMENDED IN SENATE MAY 31, 2016

AMENDED IN ASSEMBLY APRIL 5, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 2325

Introduced by Assembly Member Bonilla

February 18, 2016

An act to amend Section 103885 ~~of, and to add Section 103887 to,~~ *of* the Health and Safety Code, relating to cancer.

LEGISLATIVE COUNSEL'S DIGEST

AB 2325, as amended, Bonilla. Ken Maddy California Cancer Registry.

Existing law requires the State Department of Public Health to establish a statewide system for the collection of information determining the incidence of cancer, known as the Ken Maddy California Cancer Registry. Existing law authorizes the department to designate any demographic parts of the state as regional cancer incidence reporting areas and establish regional cancer registries to provide cancer incidence data. Existing law requires any hospital or other facility providing therapy to cancer patients within a cancer reporting area to report each case of cancer to the department or the authorized representative of the department in a format prescribed by the department. Existing law provides that if the hospital or other facility fails to report in a format prescribed by the department, the department's authorized representative is authorized to access the information from the hospital or the facility and report it in the appropriate format. In these cases, existing law requires the hospital or other health facility to reimburse the department or the authorized representative for its cost

to access and report the information. Existing law also requires any physician, dentist, podiatrist, or other health care practitioner diagnosing or providing treatment for cancer patients to report each cancer case to the department or the authorized representative of the department, except for those cases directly referred to a treatment facility or those previously admitted to a treatment facility for diagnosis or treatment of that instance of cancer.

This bill, on or after January 1, 2019, would require a pathologist diagnosing cancer to *electronically* report cancer diagnoses to the ~~department in a format prescribed by the department.~~ *department, as specified.* If a pathologist fails to report ~~in that~~ *electronically and with an approved* format, the bill would authorize the department's authorized representative to access the information from the pathologist in ~~the~~ *an* appropriate *alternative* format. In these cases, the bill would require the pathologist to reimburse the department or the authorized representative for its cost to access and report the information. The bill would require the department to prescribe the data required to be included in the reports and to *work collaboratively with stakeholders to* designate a standardized electronic format for submission of the reports.

~~This bill would also require the department to establish a pilot program to enable the department and other authorized users to conduct electronic specific data element searches for the purpose of identifying individuals who meet cancer clinical trial eligibility requirements.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 103885 of the Health and Safety Code is amended to read:

103885. (a) The director shall establish a statewide system for the collection of information determining the incidence of cancer, using population-based cancer registries modeled after the Cancer Surveillance Program of Orange County. As of the effective date of this section the director shall begin phasing in the statewide cancer reporting system. By July 1, 1988, all county or regional registries shall be implemented or initiated. By July 1, 1990, the statewide cancer reporting system shall be fully operational. Within

60 days of the effective date of this section, the director shall submit an implementation and funding schedule to the Legislature.

(b) The department may designate any demographic parts of the state as regional cancer incidence reporting areas and may establish regional cancer registries, with the responsibility and authority to carry out the intent of this section in designated areas. Designated regional registries shall provide, on a timely basis, cancer incidence data as designated by the state department to the department. The department may establish a competitive process to receive applications for, and issue, the award of a contract, grant, or allocation of funds, including, but not limited to, a cooperative agreement, subvention agreement, or any other agreement allowed by law, to an agency, including, but not limited to, a health systems agency, single county health department, multicounty health department grouping, or nonprofit professional association to operate the statewide cancer reporting system and to enter into contracts, or issue grants or funding allocations to other agencies representing a designated cancer reporting region for the purposes of collecting and collating cancer incidence data. The award of these contracts, grants, or funding allocations shall be exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. The department shall include appropriate terms and conditions in a contract, grant, or funding allocation to ensure the proper use of state funds, including provision for reimbursement of allowable costs, financial reporting, program performance reporting, monitoring of subgrants, subcontracts, or suballocations to an agency representing a designated cancer reporting region, retention and access requirements for records, data use and management, independent auditing, termination, and disposition of assets acquired under the contract, grant, or funding allocation.

(c) The director shall designate cancer as a disease required to be reported in the state or any demographic parts of the state in which cancer information is collected under this section. All cancers diagnosed or treated in the reporting area shall thereafter be reported to the representative of the department authorized to compile the cancer data, or any individual, agency, or organization designated to cooperate with that representative.

(d) (1) Any hospital or other facility providing therapy to cancer patients within an area designated as a cancer reporting area shall

report each case of cancer to the department or the authorized representative of the department in a format prescribed by the department. If the hospital or other facility fails to report in a format prescribed by the department, the department's authorized representative may access the information from the hospital or the facility and report it in the appropriate format. In these cases, the hospital or other health facility shall reimburse the state department or the authorized representative for its cost to access and report the information.

(2) Any physician and surgeon, dentist, podiatrist, or other health care practitioner diagnosing or providing treatment for cancer patients shall report each cancer case to the department or the authorized representative of the department, except for those cases directly referred to a treatment facility or those previously admitted to a treatment facility for diagnoses or treatment of that instance of cancer.

(3) On or after January 1, 2019, a pathologist diagnosing cancer shall *electronically* report cancer diagnoses to the department ~~in a format prescribed by the department.~~ *utilizing the College of American Pathologists cancer protocols or any other standardized format approved by the department.* If a pathologist fails to report ~~in that~~ *electronically and with an approved* format, the department's authorized representative may access the information from the pathologist in ~~the~~ *an* appropriate *alternative* format. In these cases, the pathologist shall reimburse the department or the authorized representative for its cost to access and report the information. *A pathologist shall not be responsible for acquiring missing or inaccessible patient demographic information not provided to him or her beyond the content of the required cancer-specific data elements.* For purposes of reports submitted pursuant to this paragraph, the department shall prescribe the data required to be included in the report and *work collaboratively with stakeholders to* designate a standardized electronic format for submission.

(e) Any hospital or other facility that is required to reimburse the department or its authorized representative for the cost to access and report the information pursuant to subdivision (d) shall provide payment to the department or its authorized representative within 60 days of the date this payment is demanded. In the event any hospital or other facility fails to make the payment to the

department or its authorized representative within 60 days of the date the payment is demanded, the department or its authorized representative may, at its discretion, assess a late fee not to exceed 1½ percent per month of the outstanding balance. Further, in the event that the department or its authorized representative takes a legal action to recover its costs and any associated fees, and the department or its authorized representative receives a judgment in its favor, the hospital or other facility shall also reimburse the department or its authorized representative for any additional costs it incurred to pursue the legal action. Late fees and payments made to the department by hospitals or other facilities pursuant to this subdivision shall be considered as reimbursements of the additional costs incurred by the department.

(f) All physicians and surgeons, hospitals, outpatient clinics, nursing homes and all other facilities, individuals, or agencies providing diagnostic or treatment services to patients with cancer shall grant to the department or the authorized representative access to all records that would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified cancer patient. Willful failure to grant access to those records shall be punishable by a fine of up to five hundred dollars ($500) each day access is refused. Any fines collected pursuant to this subdivision shall be deposited in the General Fund.

(g) (1) Except as otherwise provided in this section, all information collected pursuant to this section shall be confidential. For purposes of this section, this information shall be referred to as "confidential information."

(2) The department and any regional cancer registry designated by the department shall use the information to determine the sources of malignant neoplasms and evaluate measures designed to eliminate, alleviate, or ameliorate their effect.

(3) Persons with a valid scientific interest who are engaged in demographic, epidemiological, or other similar studies related to health who meet qualifications as determined by the department, and who agree, in writing, to maintain confidentiality, may be authorized access to confidential information.

(4) The department and any regional cancer registry designated by the department may enter into agreements to furnish confidential information to other states' cancer registries, federal cancer control

agencies, local health officers, or health researchers for the purposes of determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect. Before confidential information is disclosed to those agencies, officers, researchers, or out-of-state registries, the requesting entity shall agree in writing to maintain the confidentiality of the information, and in the case of researchers, shall also do both of the following:

(A) Obtain approval of their committee for the protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations.

(B) Provide documentation to the department that demonstrates to the department's satisfaction that the entity has established the procedures and ability to maintain the confidentiality of the information.

(5) Notwithstanding any other provision of law, any disclosure authorized by this section shall include only the information necessary for the stated purpose of the requested disclosure, used for the approved purpose, and not be further disclosed.

(6) The furnishing of confidential information to the department or its authorized representative in accordance with this section shall not expose any person, agency, or entity furnishing information to liability, and shall not be considered a waiver of any privilege or a violation of a confidential relationship.

(7) The department shall maintain an accurate record of all persons who are given access to confidential information. The record shall include: the name of the person authorizing access; name, title, address, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be open to public inspection during normal operating hours of the department.

(8) Notwithstanding any other provision of law, no part of the confidential information shall be available for subpoena, nor shall it be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding, nor shall this information be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.

(9) Nothing in this subdivision shall prohibit the publication by the department of reports and statistical compilations that do not

in any way identify individual cases or individual sources of information.

(10) Notwithstanding the restrictions in this subdivision, the individual to whom the information pertains shall have access to his or her own information in accordance with Chapter 1 (commencing with Section 1798) of Title 1.8 of the Civil Code.

(h) For the purpose of this section, "cancer" means either of the following:

(1) All malignant neoplasms, regardless of the tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia, but excluding basal cell and squamous cell carcinoma of the skin.

(2) All primary intracranial and central nervous system (CNS) tumors occurring in the following sites, irrespective of histologic type: brain, meninges, spinal cord, caudae equina, cranial nerves and other parts of the CNS, pituitary gland, pineal gland, and craniopharyngeal duct.

(i) Nothing in this section shall preempt the authority of facilities or individuals providing diagnostic or treatment services to patients with cancer to maintain their own facility-based cancer registries.

(j) It is the intent of the Legislature that the department, in establishing a system pursuant to this section, maximize the use of available federal funds.

~~SEC. 2. Section 103887 is added to the Health and Safety Code, to read:~~

~~103887. The department shall establish a pilot project to enable the department and users authorized pursuant to this chapter to conduct electronic specific data element searches of the information collected by the statewide cancer registry for the purpose of identifying individuals who meet cancer clinical trial eligibility requirements.~~

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