SENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2023-2024 Regular Session

SB 344 (Rubio)
Version: March 30, 2023
Hearing Date: April 18, 2023
Fiscal: Yes
Urgency: No
AM

SUBJECT

Ken Maddy California Cancer Registry

DIGEST

This bill revises provisions of law related to the Ken Maddy California Cancer Registry (CCR) to, among other things, allow disclosure of data in the registries if the information is utilized for the continuation of the original approved disclosure and is shared with other authorized individuals and approved by the State Department of Public Health (CDPH).

EXECUTIVE SUMMARY

According to the author and sponsors this bill will improve the effectiveness of the CCR by shortening delays and streamlining ePath reporting, resulting in improved cancer research and more advancements in cancer treatment and care. Specifically, the bill authorizes information in the CCR to be further disclosed by authorized users if it is utilized for the continuation of the original disclosure, and the original disclosure is for research that requires the researchers to participate in data sharing with other approved individuals or the information is shared with other authorized individuals and approved by the State Department of Public Health (CDPH). Additionally, the bill provides that the requirement on CDPH to maintain an accurate record of all persons who are given access to confidential information under the CCR does not extend to federal or federally designated data repositories and other authorized researchers to whom data is provided.

This bill is sponsored by the American Cancer Society Cancer Action Network, City of Hope, Public Health Institute, and the University of Southern California. The bill is supported by Susan G. Komen and Stanford Health Care. There is no known opposition. The bill passed the Senate Health Committee on a vote of 12 to 0.

PROPOSED CHANGES TO THE LAW

Existing law:

1) Requires the California Department of Public Health (CDPH) to establish a statewide system for the collection of information determining the incidence of cancer, using population-based cancer registries (known as the Ken Maddy California Cancer Registry, or CCR).
    a) Permits CDPH to designate any demographic parts of the state as regional cancer incidence reporting areas and to establish regional cancer registries.
    b) Requires designated regional registries to provide CDPH, on a timely basis, cancer incidence data. (Health & Saf. Code § 103885.)

2) Requires any hospital or other facility providing therapy to cancer patients, and any physician, dentist, podiatrist, or other health care practitioner diagnosing or providing treatment for cancer patients, to report each case of cancer to CDPH or the authorized representative of CDPH. (*Id*. at subd. (d).)

3) Requires all information collected pursuant to the CCR to be confidential, and requires CDPH to use the information to determine the sources of malignant neoplasms and evaluate measures designed to eliminate, alleviate, or ameliorate their effect. (*Id*. at para. (1) & (2) of subd. (g).)

4) Authorizes persons with a valid scientific interest who are engaged in demographic, epidemiological, or other similar studies related to health to access confidential information if they meet certain qualifications and agree, in writing, to maintain confidentiality of that information.

5) Authorizes CDPH and any regional cancer registry designated by CDPH to 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. Requires the requesting entity to agree in writing to maintain the confidentiality of the information before confidential information is disclosed, and in the case of researchers, to do both of the following:
    a) obtain approval of their committee for the protection of human subjects, as specified; and
    b) provide documentation to CDPH that demonstrates to CDPH's satisfaction that the entity has established the procedures and ability to maintain the confidentiality of the information. (*Id*. at para. (4) of subd. (g).)

6) Provides that any disclosure of information can only include the information necessary for the stated purpose of the requested disclosure, only be used for the approved purposes, and cannot be further disclosed. (*Id*. at para. (4) of subd. (g).)

7) Provides that the furnishing of confidential information to CDPH or its authorized representative in accordance with these provisions does not expose any person, agency, or entity furnishing information to liability, and is not to be considered a waiver of any privilege or a violation of a confidential relationship. (*Id*. at para. (6) of subd. (g).)

8) Requires CDPH to maintain an accurate record of all persons who are given access to confidential information. (*Id*. at para. (7) of subd. (g).)

This bill:

1) Requires the Director of CDPH to maintain a statewide registry infrastructure that maximizes and strengthens California's existing regional registry infrastructure funded through the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program.

2) Requires, instead of authorizing, CDPH to both designate any demographic parts of the state as a regional cancer incidence reporting area and establish regional cancer registries.

3) Requires a pathology laboratory diagnosing or treating a reportable case of cancer to report that cancer diagnose to CDPH.

4) Authorizes further disclosure of information if it is utilized for the continuation of the original disclosure, and one of the following criteria is met:
    a) the original disclosure is for research that requires the researchers to participate in data sharing with other approved individuals; or
    b) the information is shared with other authorized individuals and approved by the department.

5) Requires that any information shared pursuant to 4) adhere to the original approved requirements relative to usage and disclosure.

6) Provides that the recordkeeping responsibility described in 8) above does not apply to federal or federally designated data repositories and other bonafide researchers to whom data is provided.

COMMENTS

1. State need for the bill

The author writes:

California has the largest cancer registry in the nation and is recognized as one of the leading cancer registries in the world. The California Cancer Registry is a vast repository of cancer data that provides vital information to public health officers and researchers, helping to inform cancer treatment, prevention, and cures. With this data, it is possible to determine cancer risk factors and study groupings of cancers in communities. However, the means for collecting data has fallen woefully behind the times and has resulted in data not being reported to the department for an average of one-and-a-half to two years. SB 344 will improve the effectiveness of the California Cancer Registry by shortening delays and streamlining ePath reporting, resulting in improved cancer research and more advancements in cancer treatment and care.

2. Background

The Senate Committee on Health analysis provides a detailed background on the California Cancer Registry, the SEER program, and the National Program of Cancer Registries:

In 1985, the California Legislature passed a law making cancer a reportable disease, although regional cancer registries existed before it was made a mandatory reportable disease. Today there are three regional registries: the Greater Bay Area Cancer Registry, the Los Angeles County Cancer Surveillance Program operated by the University of Southern California, and the Cancer Registry of Greater California (which covers all other counties). The CCR is California's statewide cancer surveillance system, which collects all the data from the regional registries into a statewide database. The CCR and regional registries use the data to write summary reports that inform the public, local health workers, educators, and legislators about the status of cancer. Researchers may examine these data to identify areas that have high cancer rates and areas where people might benefit from cancer screening and education programs, or to look at trends in cancer diagnosis. Other uses include, but are not limited to, measuring the success of cancer screening programs; examining disparities in cancer risk, treatment and survival; examining treatment choices and other predictors of survival; responding to public concerns and questions about cancer; and, conducting research to find the causes and cures of cancer. The CCR and regional registries are permitted to release patient contact information to qualified researchers, who may contact patients to find out if they want to participate in a research study. However, information is only released to qualified researchers under tightly controlled circumstances where the research has first been approved by the Committee for the Protection of Human Subjects.

The SEER Program of the National Cancer Institute (NCI) is the authoritative source of information on cancer incidence and survival for the nation as a whole. SEER currently collects and publishes cancer incidence and survival data from

population-based registries covering approximately 48% of the U.S. population. NCI staff work with the North American Association of Central Cancer Registries to guide all state registries to achieve data content and compatibility acceptable for pooling data and improving national estimates. The SEER team is developing computer applications to unify cancer registration systems and to analyze and disseminate population-based data. Use of surveillance data for research is being improved through web-based access to the data and analytic tools, and linking with other national data sources.

The National Program of Cancer Registries (NPCR) is a program established by the Centers for Disease Control and Prevention to provide funding and technical assistance to statewide, population-based cancer registries. NPCR supports states and territories to improve existing cancer registries; plan and implement registries where none existed; develop model legislation and regulations for states to enhance the viability of registry operations; set standards for data completeness, timeliness, and quality; provide training for registry personnel; and, help establish a computerized reporting and data processing system. In 2006, NPCR launched the Electronic Pathology (ePath) Implementation Project to test a model for automated electronic capture and reporting of cancer registry data to central cancer registries. Following initial pilot programs, ePath has expanded to all 50 states and includes many more national and regional laboratories. In California, AB 2325 (Bonilla, Chapter 354, Statutes of 2016) required pathologists to use ePath to report cancer diagnoses beginning on January 1, 2019.[1]

3. Bill authorizes additional sharing of confidential information

The bill provides that an authorized disclosure of information may be further disclosed if the information utilized for the continuation of the purpose for which the original disclosure was approved, and either limited circumstance is met: (1) the original disclosure is for research that requires the researchers to participate in data sharing with other approved individuals; or (2) the information is shared with other authorized individuals and approved by the CDPH. Any information shared under this authorization is required to adhere to the original approved requirements related to usage and disclosure. The bill also provides that the recordkeeping responsibility of CDPH regarding maintaining an accurate record of all persons who are given access to confidential information in the CCR does not extend to federal or federally designated data repositories and other bona fide researchers to whom data is provided.

According to the author and sponsors these changes will improve the effectiveness of the CCR by shortening delays and streamlining ePath reporting, resulting in improved cancer research and more advancements in cancer treatment and care. They note that

[1] Sen. Comm. on Health analysis of SB 344 (2023-34 reg. sess.) as amended March 20, 2023 at pp. 3-4.

the National Institute of Health (NIH) Policy for Data Management and Sharing requires that any NIH funded or conducted research, in whole or in part, that results in the generation of scientific data must comply with data sharing requirements, which is defined as the act of making scientific data available for use by others, including the larger research community, institutions, the public, and via online repositories. The goal of the bill is to align CCR data sharing policies and practices with NIH policies that generally require study data to be largely shareable without restrictions. They posit that the current non-redisclosure policy and recordkeeping provisions in California law hamper the ability of California researchers to participate in, and California data to be used in, NIH funded research, potentially hampering the ability to prevent and treat cancer not only in this state but across the nation.

4. Proposed amendments

The author may wish to make the following clarifying amendments to the bill. First, the author may wish to include "or entities" after "individuals" under the two limited circumstance for further disclosure to ensure the statute is not interpreted to only authorize further disclosure to an individual and not an entity, such as a cancer registry. Additionally, the author may wish to delete the limitation on CDPH's requirement to maintain an accurate record of all persons given access to confidential information to as the language it was cross-referencing was removed by the amendments made in the Senate Health Committee.

The specific amendments are as follows:

Amendment 1

On page 7, in line 22, after "individuals" add:

or entities

Amendment 2

On page 7, in line 23, after "individuals" add:

or entities

Amendment 3

On page 8, delete lines 2 through 4.

5. Statements in support

The sponsors of the bill, the American Cancer Society Cancer Action Network, the City of Hope, the Public Health Institute, and the University of Southern California, write in support stating:

> [T]he real-time benefit of reporting through ePath—if fully and completely implemented—will have significant benefits for clinical trials. Failure to fully

implement ePath means a two-year delay in reporting of a cancer case, which eliminates that value of the data for clinical trial enrolment. Currently, only 3% of adults diagnosed with cancer participate in clinical trials, those numbers are much lower for those of racial and ethnic minorities.

Furthermore, provisions in current law limit the CCR, including the regional registries, to allow data re-disclosure by approved cancer researchers to comply with National Institutes of Health data sharing requirement with federal data repositories and controlled data sharing with other legitimate research endeavors. Outdated approaches to data collection and data sharing thwart vital research into cancer treatment and cures, preventing progress that would save lives. SB 344 will help address this problem by updating procedures that ensure that approved researchers have access to timely data while ensuring necessary data protections and privacy are strengthened and maintained.

SUPPORT

American Cancer Society Cancer Action Network (sponsor)
City of Hope (sponsor)
Public Health Institute (sponsor)
University of Southern California (sponsor)
Stanford Health Care
Susan G. Komen

OPPOSITION

None known

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation:

AB 2325 (Bonilla, Ch. 354, Stats. 2016) required, beginning January 1, 2019, a pathologist diagnosing cancer to report cancer diagnoses to the CDPH utilizing electronic means in a standardized format approved by CDPH.

PRIOR VOTES:

Senate Health Committee (Ayes 12, Noes 0)

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