SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 371
AUTHOR: Caballero
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SUBJECT: Health information technology

SUMMARY: Establishes the California Health Information Technology (HIT) Advisory Committee and the position of Deputy Secretary for HIT within the California Health and Human Services Agency to provide information and advice to the Secretary on HIT and create an annual report. Requires a health information organization to be connected to the California Trusted Exchange Network and to a qualified national network to facilitate bidirectional exchange of patient data across networks. Requires a health care provider, health system, health plan, or health insurer that engages in health information exchange to do so in accordance with specified standards. Requires the Department of Health Care Services to apply for funding made available through the American Rescue Plan Act of 2021 or the Medicaid Information Technology Architecture program for specified purposes.

Existing federal law:

1) Establishes the federal American Recovery and Reinvestment Act of 2009 (ARRA), including the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, to authorize Medicare and Medicare incentive payments to acute-care hospitals and physicians who meaningfully use certified electronic health record (EHR) technology. [42 U.S.C §300jj]

2) Establishes, under federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which among various provisions, mandates industry-wide standards for health care information on electronic billing and other processes; and, requires the protection and confidential handling of protected health information. [42 U.S.C. §300gg, 29 U.S.C. §1181, et seq., and 42 U.S.C. §1320d, et seq.]

3) Establishes the 21st Century Cures Act of 2016 (Cures Act), which among other provisions, prohibits a HIT developer or entity from taking actions that constitute information blocking, as defined, or inhibiting the appropriate exchange, access, and use of electronic health information; and establishes a process for the development of a "trusted exchange network." [42 U.S.C §300jj]

4) Defines "information blocking" as a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and if conducted by a HIT developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or if conducted by a health care provider, such provider knows that such practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. [42 U.S.C §300jj-52]

Existing state law:

1) Creates, in the event the California Health and Human Services Agency (CHHS) applies for and receives federal funds made available through the ARRA for HIT and exchange, the California HIT and Exchange Act and Fund. [HSC §130250.1 and §130255]

2) Requires, pursuant to the Confidentiality of Medical Information Act (CMIA), certain businesses organized for the purpose of maintaining medical information, or offering software or hardware to consumers (including a mobile application or other related device designed to maintain medical information)to maintain the same standards of confidentiality required of a health care provider with respect to medical information disclosure. Subjects these businesses to the same penalties for improper use and disclosure of medical information as a health care provider. [CIV §56.06]

3) Requires every health care provider to establish and implement appropriate administrative, technical, and physical safeguards to protect the privacy of a patient's medical information, and, reasonably safeguard confidential medical information from any unauthorized access or unlawful access, use or disclosure. [HSC §1280.18]

4) Makes violations that results in economic loss or personal injury to a patient punishable as a misdemeanor, and in addition to any other remedies available in law, permits an individual to bring an action against a person or entity who has negligently released confidential information or records concerning him or her for actual or other administrative or civil damages, as specified. [CIV §56.36]

5) Establishes the Department of Health Care Services (DHCS), which administers the Medi-Cal program. [WIC § 14000 et. seq.]

This bill:

1) Permits CHHS, if funds are available, upon appropriation by the Legislature, to utilize the California HIT and Exchange Fund for both of the following:

    a) Provide grants to small physician or dental practices, community health centers, critical access hospitals, and other safety net providers to help them implement or expand their use of HIT and connect to qualified health information networks; and,
    b) Contract with experienced organizations to provide direct data exchange technical assistance to safety net providers.

2) Establishes, the position of Deputy Secretary for HIT (deputy secretary) within CHHS, to be appointed by the Governor and confirmed by the Senate, to serve as a single point of contact for internal and external stakeholders for HIT programs that interact with the state government, and coordinate with:

    a) The federal Office of the National Coordinator (ONC) for HIT; and,
    b) The Federal Communications Commission regarding availability and implementation of broadband internet services for telehealth and health information exchange (HIE) in California.

3) Requires the deputy secretary to establish and convene the California HIT Advisory Committee (advisory committee), whose members are to be appointed by the deputy secretary for three-year terms. Requires terms of the members to be staggered such that no more than one-third of the advisory committee seats become open in any one year.

4) Establishes responsibilities of the advisory committee and requires it to be composed of health care stakeholders and experts, including representatives of:

   a) DHCS;
   b) Department of Managed Health Care;
   c) Department of Insurance;
   d) Department of Public Health (CDPH);
   e) California Health Benefit Exchange;
   f) Public Employees Retirement System;
   g) Health plans and insurers;
   h) Physicians, including those with small practices;
   i) Hospitals and clinics, long-term care facilities, or behavioral health or substance use disorder facilities;
   j) Consumers;
   k) Organized labor, including a member with expertise in the Employment Retirement Income Security Act of 1974;
   l) A member with privacy and security expertise;
   m) HIT professionals;
   n) Community health information organizations; and,
   o) Community-based organizations providing social health services.

5) Requires a health information organization to be connected to the California Trusted Exchange Network (CTEN) and, either through the CTEN or independently, to a qualified national network to facilitate bidirectional exchange of patient data across networks.

6) Requires a health care provider, health system, health plan, or health insurer that engages in HIE to do so in accordance with the Interoperability Standards Advisory published and maintained by the federal ONC for HIT.

7) Requires DHCS to apply for federal funding made available through the American Rescue Plan Act of 2021 or the Medicaid Information Technology Architecture (MITA) program. Requires funds received through MITA to be used for all of the following purposes:

   a) Creating a unified state HIE gateway, using an application programming interface to facilitate bidirectional communication between data holders within state government and health information organizations, national data exchange networks, direct interfaces with electronic health care record systems, and mobile health applications. Requires the primary purpose of the unified state HIE gateway to be to improve the bidirectional exchange of data between state sources and health care providers, including the Medi-Cal program, the California Reportable Disease Information Exchange, the California Immunization Registry, and the Controlled Substance Utilization Review and Evaluation System;
   b) Providing shared services to promote data exchange, in consultation with the California HIT Advisory Committee;

c) Supporting efforts by qualified health information organizations to expand their services territories into geographic regions not currently served by a regional health information organization; and,
d) Providing technical assistance and support to health care providers, including small physician and dental practices, community health centers, public and critical access hospitals, and other safety net providers.

8) Finds and declares that California needs to enhance its robust health care data exchange to achieve greater care coordination and to continue moving the health care system toward value-based care. States the goal of promoting data exchange is to leverage a "network of networks" approach, utilizing existing technology standards to facilitate the seamless flow of data between providers, regardless of the technology they utilize.

9) States the federal ONC for HIT's Cures Act Final Rule and the federal Centers for Medicare and Medicaid's Interoperability and Patient Access Final Rule provide a policy framework and requirement for new methods of HIEs, driven by patient access and control of their own data. These rules will also require providers, health care service plans, health insurers, health information organizations, and all other actors to make all patient data available at the point of care. California should build on this federal framework to facilitate access, exchange, and use of health data across the state.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* According to the author, HIT can allow health care providers to access patient medical records and information in a safe, secure, and timely manner. This data exchange can take many forms, including HIEs, national data exchange networks, and app-based exchange. These forms of data exchange provide confidential access to a patient's unique medical history, regardless of where they go for care, which allows providers to give individualized care based on the patient's history. This bill creates a comprehensive plan for HIE access in all medical practices across the state by building support where it is needed for smaller establishments, creating more streamlined access for providers to public health data, leveraging federal funding, and re-establishing the role of Deputy Secretary of HIT and the eHealth Coordinating Committee under CHHS.

2) *Background.* In 2009, SB 337 (Alquist, Chapter 180, Statutes of 2009) was passed with the intent that California develop a statewide HIT infrastructure to improve California's health care system using funding provided through the HITECH Act as part of ARRA to encourage the adoption and meaningful use of HIT and exchange. As part of this action, the state recognized that the full benefit of HIT cannot be realized until EHR systems supporting the secure exchange of individual health records are in place and used by health care providers, payers, patients, and other individuals throughout the state, and across state boundaries. HIE necessarily includes the sharing of private health records and information of individuals. Establishing the security of individual privacy rights and confidentiality of personal health and medical records is of paramount importance to creating public confidence in any broad-based EHR system. Ensuring transparent accountability, governance, and oversight are critical components to maintaining the public's trust.

3) *HIE California landscape.* In order to exchange health information, health care providers often need intermediaries, or health information organizations (HIOs) to assist. Some big EHR vendors have created private HIOs to enable data sharing among their own customers, while other groups of providers in a region have created nonprofit organizations to manage data interfaces, master patient indexes, repositories, data sharing agreements and applications, etc. According to a report published in January of 2019 by the California Health Care Foundation (CHCF), an estimated 187 hospitals statewide participate in regional HIOs and 200 hospitals do not. Many regional HIOs are struggling to find sustainable financial footing to prove their value in the face of well-funded private alternatives. Funding under HITECH has created substantial growth in both public and private HIOs but with minimal coordination at the state-level. While regional dynamics have created uniquely local solutions, some regions and entities have fallen behind or left vulnerable to changing market forces. There are nine major regional HIOs in California but many counties in the central region of California have no HIO with the exception of Tulare, Fresno, Merced, Stanislaus, San Joaquin and Santa Clara. Del Norte is the only northern county not participating in an HIO. In a March 2021 update report, CHCF indicates the HIE ecosystem across California is composed of a combination of direct exchange between providers, the use of national networks, and over 15 regional HIOs. This fragmented model delivers inconsistent and incomplete solutions that do not provide all of the critical information needed to care for the state's residents, do not provide access to all the service providers who need data, and do not scale to provide state health care leaders with the access to data they need. Coupled with restrictive, confusing, and ambiguous data exchange rules, the exchange environment does not and cannot adequately enable initiatives to improve care quality; enhance access to medical, social, and public health services; reduce disparities; and lower costs for residents, counties, and the state.

4) *Medi-Cal.* California's Medi-Cal HIE Onboarding Program or CalHOP, administered by the DHCS, is intended to provide Medi-Cal providers with assistance participating in HIOs. Up to $50 million is available from a federal matching program for counties/providers to participate in the program. Five million dollars from the state General Fund was approved in the 2018 Budget Act along with expenditure authority for another $45 million in federal funding for CalHOP. With limited funding, CalHOP is not intended to be a reimbursement program. DHCS committed to exploring other mechanisms to help Medi-Cal providers cover the costs to access and use HIE services. According to a CalHOP 2019 meeting, a survey of Medi-Cal providers indicates that only 26% of all providers were connecting to an HIO and 14% were planning to connect within 12 months. Only 17% of ambulatory practices were connecting to an HIO and 8% were planning to connect within 12 months. Sixty-three percent of respondents indicated that the cost of connecting to an HIO (including HIO subscription fees, costs to modify EHR systems, etc.) was a significant or moderate barrier. Seventy-three percent of ambulatory practices indicated that the cost of connecting to an HIO was a significant or moderate barrier. Fifty-one percent of respondents indicated that they most valued "assistance with building technical interfaces from their EHR to the HIO.

5) *CTEN.* According to the California Association of HIEs (CAHIE), unlike other states that chose to establish a single HIE or public-private network, California's strategy for health information sharing relies on regional and enterprise initiatives, each one meeting the unique needs of its participants. CAHIE was formed to promote collaboration to solve difficult policy and technology problems, and to facilitate statewide health information sharing through voluntary self-governance. Long before the HIT boom, California had a community- and enterprise-oriented, decentralized approach to health information sharing. This approach continued during the HITECH era, with the development of the CTEN, a framework designed to provide the most flexibility to adapt to California's complex healthcare ecosystem and emphasize local autonomy to create and operate services that best meet the needs of local users, all supported by voluntary self-governance as well

as local and state government coordination. The CTEN is designed to be more efficient, more agile, and more flexible than national networks while remaining compatible with them. Unlike most other networks, the CTEN allows its participants to define the method and technical standards they will use to share health information.

6) *Governor's 2021-22 budget*. The Governor's budget summary includes the following:

> It is imperative that the state expand the use of clinical and administrative data to better understand the health and social needs of individual patients in order to achieve high-quality, efficient, safe, and timely service delivery while improving outcomes. These goals can be accomplished by building and supporting the infrastructure and information systems to facilitate secure and appropriate exchange of electronic health information among health care providers. Despite significant federal investment over the past ten years for adoption of EHR and creation of HIEs, most patients' medical information, including clinical histories, medications, and test results, is stored on paper or across hundreds of disparate EHR systems. The goals of improved health outcomes and affordability cannot be achieved without unified patient health records and digital infrastructure to support a more integrated provision of health and human services. To further build on the promise of HIE, the Administration is interested in accelerating the utilization and integration of HIEs as part of a network that receives and integrates health data for all Californians. The building and operation of the network of exchanges will leverage existing investments in HIE and look for additional federal funding in alignment with federal interoperability rules. To do this the state must:
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> a) Enable the right access to health information at the right time resulting in improved health and outcomes for all Californians;
> b) Identify and overcome the barriers to exchanging health information between public programs, as well as with California providers and consumers; and
> c) Engage consumers and their providers in managing medical, behavioral and social services through appropriate, streamlined access to electronic health information.
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> The Administration envisions an environment where health plans, hospitals, medical groups, testing laboratories, and nursing facilities—at a minimum, as a condition of participating in state health programs such as Medi-Cal, Covered California and CalPERS—contribute to, access, exchange, and make available data through the network of HIEs for every person.

7) *New federal requirements for sharing EHI*. The federal ONC is responsible for implementation of key provisions in the 21st Century Cures Act dealing with interoperability, supporting access, exchange, and use of electronic health information, including addressing information blocking. Among other things, the ONC final rule implements requirements to support patients' access to their electronic health information in a form that is convenient for patients, such as making the information more electronically accessible through the adoption of standards and certification criteria. The ONC final rule modifies specified health IT certification criteria and ONC Health IT Certification programs in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs. The ONC final rule establishes application programming interface (API) requirements, including for patients' access to their health information without special effort. The API approach also supports health care providers' independence to choose the "provider-facing" third-party services they want to use to interact with the certified API technology they have acquired. In addition, the ONC final rule provides the federal Secretary of Health and Human Services' interpretation of the information blocking definition as established in the Cures Act and the application of the information blocking provision by identifying reasonable and necessary

activities that would not constitute information blocking. Many of these activities focus on improving patient and health care provider access to exchange health information and promoting competition.

According to a March 2021 CHCF report on lessons learned from other states for California, new federal regulations that take effect as early as 2021 will dramatically reshape the landscape and create an opportunity for California to act. These new standards and requirements for expanding data sharing, include requiring hospitals to notify primary care providers when hospitals admit, discharge, or transfer patients; requiring health plans and payers (including Medicaid) to make patient data available; allowing patients to access a single, complete health record from all their providers and health plans; and allowing patients and care teams to access a list of health plan providers, and eventually, telling them which providers are accepting new patients. The goal of the federal regulations is to ensure that a greater amount of data flows through the delivery system and is broadly accessible to improve patient and public health outcomes, while maintaining strict privacy and security standards. The cost to build or improve the technology to meet the federal mandates falls on the affected entities, such as the EHR vendors, hospitals, or payers. However, there is significant federal funding, ranging from 50% to 100% of the cost, available to state Medicaid agencies for planning and implementing systems to be in compliance with Medicaid regulations. There are two requirements to get the federal funding: a) Funding is only available for those costs of the project that benefit the Medicaid population; and, b) to be eligible for federal funds, accountability and oversight that show if the statewide health data network is meeting the benchmarks and outcomes outlined in the grant documents must rest with a state entity like CHHS that includes the state's Medicaid agency. COVID-19 relief funds also create another opportunity to draw down federal funds to advance a statewide health data network.

8) *Other states*. The CHCF lessons learned report indicates Michigan, Maryland, Nebraska, and New York are nationally recognized as having robust statewide health data networks that ensure access to a nearly complete record of a patient's health care data timely and securely. Based on these models, the CHCF report identifies as a framework for success: a) The state has to take a strong leadership role; b) A multi-stakeholder body with public, nonprofit, and private business representation should provide operational oversight; and, c) the network must tap public and private funding. Other recommendations for California policy makers include:

   a) Keep the statute to top-tier policy issues such as governance, participation by providers and payers, consumer access to the data, data privacy, and financing. The statute should describe the state role and the role of private and public partners in administration and operation of the network.
   b) Recognize that use cases must drive the expansion of HIE over time. Incrementally implement solutions, starting with a problem most people believe should be addressed.
   c) Provide incentives for participation in the networks and use enforcement "sticks" for entities that do not fully participate.

9) *Assembly Health Committee HIE hearings.* The Assembly Committee on Health held two hearings on HIE in which experts discussed California's current HIE landscape and considerations for policymakers with respect to statewide HIE. On the topic of the new federal rules, one speaker explained that entities mandated to participate include Medicaid and CHIP fee-for-service providers, managed care plans, prepaid inpatient health plans,

prepaid ambulatory health plans, which includes in California county mental health plans, Drug Medi-Cal ODS and dental plans, Cal Medi-Connect plans (as well as Medicare Advantage plans), and health plans on the federally facilitated exchange (this does not include Covered California as it is a state based exchange). As a key takeaway, the speaker indicated this federal rule is a big leap forward for empowering consumer engagement and clinical care coordination but this sets the floor, not the ceiling, for what is possible. California should leverage this solid foundation and federal approach to inform statewide options: use cases, mandated participation, common standards, and, modern technologies. Another speaker, who is a past California Deputy Secretary for HIT, suggested policymakers consider and agree upon what are the state's priorities that HIE can enable: pandemic response, caring for complex patients, quality and encounter reporting, integrated physician and behavioral health, affordability, transformation and value based-care, or something else.

10) *Related legislation.* AB 1131 (Wood) requires, by January 1, 2023, health plans, hospitals, medical groups, testing laboratories, and nursing facilities, to at a minimum, contribute, access, exchange, and make available data through the network of health information exchanges for every person, as a condition of participation in a state health program, including Medi-Cal, Covered California, and CalPERS. States legislative intent to enact legislation that would expand the use of clinical and administrative data and further build on the promise of HIE, including specified strategies for achieving these goals. *AB 1131 is set for hearing in the Assembly Health Committee on April 6, 2021.*

11) *Prior legislation.* SB 270 (Alquist, Chapter 510, Statutes of 2010) clarifies existing law related to delays in reporting unauthorized access to, and use or disclosure of, a patient's medical information to the CDPH, makes other specified clarifications, and extends sunset for California Office of Health Insurance Portability and Accountability Act of 2001 (HIPAA) Implementation (CalOHI).

SB 337 (Alquist, Chapter 180, Statutes of 2009) authorizes CHHS to apply for federal HIT and exchange funding and would, if no application is made by a certain date, require selection of a state-designated qualified nonprofit agency for the purposes of submitting an application for federal HIT and exchange funding. Requires, if CHHS applies for and receives federal HIT and exchange funding, creation of the California HIT and Exchange Fund in the State Treasury.

SB 853 (Committee on Budget, Chapter 717, Statutes of 2010) authorizes the state to contract with a qualified nonprofit entity to operate a federally-funded HIE. It establishes a process for a nonprofit entity to implement a statewide collaborative process for expanding capacity for electronic HIE, as well as, establishes the parameters and requirements of entering into a contract with a nonprofit entity for this purpose.

SB 441 (Galgiani of 2019) would have enacted the California Interoperability Enforcement Act to regulate EHR vendors operating in California and require the office to review federal law and policy for opportunities to regulate EHR vendors and to establish an interoperability enforcement structure. SB 441 would establish a Complaint and Technical Assistance Division within the office and the Interoperability Enforcement Fund, which would be available, upon appropriation, to fund the administration of these provisions. *SB 441 was scheduled but not heard in the Senate Health Committee.*

12) *Support*. The California Medical Association, the sponsor of this bill, writes over the past twelve years, since the passage of ARRA, health care data exchange has expanded greatly in this state. There are multiple regional health HIOs, such as LANES, OCPRHIO, San Diego Health Connect, and others, as well as vendor-based national networks (such as Carequality, Commonwell, and eHealth exchange) and other newer data exchange technologies. But the implementation and spread of data exchange has been uneven among providers, often based on access to robust EHRs and technical assistance. Moreover, as the federal ARRA funding has waned, the state infrastructure that supported the early development of data exchange in this state has dried up. Physicians and other stakeholders, whose data needs have expanded greatly over time, have been left uncertain about how to access data they need and who is in charge of the state's data apparatus. To solve this problem, this bill would reinstate the Deputy Secretary of HIT within CHHS, which previously existed from 2010-2015, to coordinate across departments inside and outside of the agency to ensure that health IT projects are responsive and coordinated. The new Deputy Secretary will coordinate multiple functions to promote data exchange between and among the state, physicians, and other health care providers and organizations. These functions could include developing shared services, such as a master patient index, and streamlining bidirectional access to data sources within the state, such as the California Reportable Disease Information Exchange (CalREDIE), the California Immunization Registry (CAIR), and the Controlled Substance Utilization and Review System (CURES) database. While physicians are able to access these data sources currently, it involves building multiple interfaces, and is generally only for the purposes of putting data in, not taking it back out. This limits their ability to utilize data in their clinical practices. Finally, and perhaps most importantly, the bill creates a pathway for the state to access federal funding through MITA funding. This line of federal funding provides a 90% federal match for the build out of new infrastructure, and 75% match for maintenance in future years. California can leverage this funding to support our efforts.

    The California Hospital Association writes this bill provides the framework for statewide solutions that will enable many more providers to securely share health information and seeks to create an exchange gateway for state data resources that facilitates information exchange between state sources and health care providers, and establishes a state leadership role responsible for coordinating statewide efforts and an Advisory Committee composed of varied health care stakeholders. These are all essential steps to ensure the thoughtful prioritization of long-term investments and to inform future policies and programs that enhance HIE. This bill will facilitate statewide HIE for 40 million Californians by building upon national standards of interoperability and leveraging the longstanding activities of our hospitals, clinics, and physicians.

13) *Oppose Unless Amended*. The Electronic Frontier Foundation (EFF) writes that privacy is too important and pressing to consign to an advisory committee. With so many questions and so few answers about how the pandemic has affected medical privacy, it would be best to seek answers before setting new policy. In its legislative findings section, this bill states, "The COVID-19 pandemic has exposed real impediments in how public health data is shared among providers, laboratories, and state and local public health agencies." It is not clear from the bill text what those "impediments" may be. But EFF hopes that it is not referring to privacy restrictions. Based on what we know from reflecting on this pandemic so far, it is not yet clear how public health data has been shared, which private companies have received any of that data, what privacy restrictions may have been placed on that sharing, and, if so, how such restrictions affected the flow of necessary data. EFF appreciates that the advisory council includes a person with "privacy and security expertise" as well as a representative of the organized labor

community. EFF would like to see the commitment to considering these issues strengthened; therefore, EFF respectfully asks that the bill clearly express a commitment to privacy, security, equity and worker concerns—and also require that any the authorization of any funding is preceded by careful consideration of these issues.

14) *Policy question.* In discussions about state HIE in California there are tensions associated with control at the provider and plan level with regard to patient data, regional exchange infrastructure where it exists, and movement toward a statewide central repository of patient data. One of many important lessons learned from COVID-19 is how important it is for a successful response to have accurate and trusted data for understanding and reducing the rate of community infection, hospitalizations and deaths; recognizing potential new variants that might emerge with each additional case; and, ensuring equitable access to testing and distribution of the state's limited vaccine supply. Does the data infrastructure envisioned in this bill put California in the best possible position to address future pandemics and the state's current health system needs?

SUPPORT AND OPPOSITION:

Support: California Medical Association (sponsor)
California Dental Association
California Hospital Association
Kaiser Permanente
Sutter Health

Oppose: Electronic Frontier Foundation (unless amended)

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