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

SB 582 (Becker)
Version: April 17, 2023
Hearing Date: April 25, 2023
Fiscal: Yes
Urgency: No
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SUBJECT

Health records: EHR vendors

DIGEST

This bill requires EHR vendors to execute the California Health and Human Services Agency Data Exchange Framework if the stakeholder advisory group decides to develop standards for their inclusion. This bill places certain guidelines on the fees that can be charged by these vendors to enable compliance with the framework.

EXECUTIVE SUMMARY

Recent legislation carried out through the budget process required the California Health and Human Services Agency (CHHS), along with its departments and offices and in consultation with stakeholders and local partners, to establish the CHHS Data Exchange Framework ("DxF") to include a single data sharing agreement and common set of policies and procedures that will leverage and advance national standards for information exchange and data content, and that will govern and require the exchange of health information among health care entities and government agencies in California. A stakeholder advisory has been convened to advise CHHS on development of the DxF.

Responding to concerns that electronic health record (EHR) vendors have been charging exorbitant fees to help facilitate the transition to information sharing through the DxF, this bill requires the stakeholder group to determine whether standards should be developed to incorporate EHR vendors into the DxF. The bill would then specifically require any fees charged by EHR vendors to be reasonable in compliance with federal law.

This bill is sponsored by the California Medical Association. It is supported by the California Orthopedic Association and the California State Association of Psychiatrists. It is opposed by OCHIN and the California Telehealth Network. This bill passed out of the Senate Health Committee on a vote of 11 to 0.

PROPOSED CHANGES TO THE LAW

Existing federal law:

1) Establishes the Health Insurance Portability and Accountability Act (HIPAA), which provides privacy protections for patients' protected health information and generally prohibits a covered entity, as defined (health plan, health care provider, and health care clearing house), from using or disclosing protected health information except as specified or as authorized by the patient in writing. (45 C.F.R. § 164.500 et seq.)

2) Provides that if HIPAA's provisions conflict with a provision of state law, the provision that is the most protective of patient privacy prevails. (45 C.F.R. § 164.500 et seq.)

3) Requires the fees an action charges, in connection with the 21st Century Cures Act, to be:
    a. based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;
    b. reasonably related to the actor's costs of providing the type of access, exchange, or use of electronic health information to, or at the request of, the person or entity to whom the fee is charged;
    c. reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and
    d. based on costs not otherwise recovered for the same instance of service to a provider and third party. (45 C.F.R. § 171.302(a)(1).)

4) Prohibits the above fees from being based on:
    a. whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor;
    b. sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the electronic health information;
    c. costs the actor incurred due to the health IT being designed or implemented in a non-standard way, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information;
    d. costs associated with intangible assets other than the actual development or acquisition costs of such assets;
    e. opportunity costs unrelated to the access, exchange, or use of electronic health information; or

f. any costs that led to the creation of intellectual property, if the actor charged a royalty for that intellectual property pursuant to 45 C.F.R. § 171.303 and that royalty included the development costs for the creation of the intellectual property. (45 C.F.R. § 171.302(a)(2).)

Existing state law:

1) Requires the California Health and Human Services Agency (CHHS), along with its departments and offices and in consultation with stakeholders and local partners, to establish the CHHS Data Exchange Framework ("DxF") to include a single data sharing agreement and common set of policies and procedures that will leverage and advance national standards for information exchange and data content, and that will govern and require the exchange of health information among health care entities and government agencies in California. (Health & Saf. Code § 130290(a).)

2) Requires the DxF to align with state and federal data requirements, including the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) (HIPAA), the Confidentiality of Medical Information Act of 1996 (Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code) (CMIA), and other applicable state and federal privacy laws related to the sharing of data among and between providers, payers, and the government, while also streamlining and reducing reporting burdens. The DxF should function to enable and require real-time access to, or exchange of, health information among health care providers and payers through any health information exchange network, health information organization, or technology that adheres to specified standards and policies. (Health & Saf. Code § 130290(a)(2)-(3).)

3) Defines "health information" to mean:
    a) for hospitals, clinics, and physician practices, at a minimum, the United States Core Data for Interoperability Version 1, until October 6, 2022. After that date, it shall include all electronic health information as defined under federal regulation in Section 171.102 of Title 45 of the Code of Federal Regulations and held by the entity; or
    b) for health insurers and health care service plans, at a minimum, the data required to be shared under the Centers for Medicare and Medicaid Services Interoperability and Patient Access regulations for public programs as contained in United States Department of Health and Human Services final rule CMS-9115-F, 85 FR 25510. (Health & Saf. Code § 130290(a)(4).)

4) Requires, on or before January 31, 2023 and in alignment with existing federal standards and policies, the following health care organizations to execute the DxF data sharing agreement:

a) general acute care hospitals;
b) physician organizations and medical groups;
c) skilled nursing facilities that currently maintain electronic records;
d) health plans and disability insurers that provide hospital, medical, or surgical coverage, as specified;
e) clinical laboratories, as specified, and that are regulated by the State Department of Public Health; and,
f) acute psychiatric hospitals. (Health & Saf. Code § 130290(f).)

5) Requires, on or before January 31, 2024, the entities listed above to exchange health information or provide access to health information to and from every other entity so listed in real time as specified by CHHS pursuant to the DxF data sharing agreement for treatment, payment, or health care operations, except as provided. (Health & Saf. Code § 130290(b).)

6) Requires CHHS to convene a stakeholder advisory group, no later than September 1, 2021, to advise on the development and implementation of the DxF, and requires the stakeholder advisory group to inform and advise CHHS on health information technology (IT) issues, including addressing the privacy, security, and equity risks of expanding care coordination, health information exchange, access, and telehealth in a dynamic technological, and entrepreneurial environment, where data and network security are under constant threat of attack. (Health & Saf. Code § 130290(c).)

7) Requires CHHS, on or before July 31, 2022, to develop in consultation with the stakeholder advisory group a strategy for unique, secure digital identities capable of supporting master patient indices to be implemented by both private and public organizations in California. (Health & Saf. Code § 130290(h).)

8) Provides, pursuant to the California Constitution, that all people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy. (Cal. Const., art. I, § 1.)

9) Establishes the CMIA, which establishes protections for the use of medical information. (Civ. Code § 56 et seq.)

10) Prohibits providers of health care, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to certain exceptions. (Civ. Code § 56.10.)

11) Provides that every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall do so in a manner

that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall be subject to remedies and penalties, as specified. (Civ. Code § 56.101.)

12) Provides that any provider of health care, a health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records shall be subject to damages in a civil action or an administrative fine, as specified. (Civ. Code § 56.36.)

This bill:

1) Requires the stakeholder advisory group to consider whether standards for including EHR vendors in the DxF would be appropriate and, if determined to be appropriate, to develop those standards.

2) Defines "EHR vendor" to mean a company that develops and provides real-time, patient-centered records that make information available securely to authorized users in a digital format capable of being shared with other providers across more than one health care organization.

3) Provides that if the stakeholder group develops standards for including EHR vendors in the DxF, they shall execute the DxF data sharing agreement no later than 12 months after the completion of the standards, and in alignment with existing federal standards and policies.

4) Requires any fees charged by an EHR vendor to enable compliance with the DxF to be reasonable, consistent with Section 171.302(a) of Title 45 of the Code of Federal Regulations.

5) Provides that reasonable fees shall be sufficient to include the cost of enabling the collection and sharing of all data required to be exchanged, as specified in the DxF data sharing agreement.

6) Authorizes CHHS, in consultation with the stakeholder advisory group or a subsequent governing board, as part of any other oversight activities authorized and developed, to establish administrative oversight and enforcement authority, including the imposition of fines and penalties against an EHR vendor that is found not in compliance with the federal standards required.

COMMENTS

1. Federal law promoting health information interoperability

The 21st Century Cures Act was passed by the federal government to promote health information interoperability. The act includes provisions that prohibit "information blocking" by certain actors, including health information networks, health information exchanges, health IT developers, and health care providers.

The term "information blocking" means, with respect to the access, use, and exchange of qualified electronic health records and other health IT, business, technical, and organizational practices that prevent or materially discourage the access, exchange, or use of electronic health information that the actor knows or should know are likely to interfere with the access, exchange, or use of electronic health information. Such practices include charging unreasonable prices or fees (such as for health information exchange, portability, interfaces, and full export of health information) that make accessing, exchanging, or using electronic health information cost prohibitive.

Attendant regulations provide guidelines for charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using electronic health information that will not be considered information blocking. Generally, such fees must be based on objective and verifiable criteria that are uniformly applied; reasonably related to the actor's costs of providing the type of access, exchange, or use of electronic health information to, or at the request of, the person or entity to whom the fee is charged; reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and based on costs not otherwise recovered for the same instance of service to a provider and third party.

2. California's Data Exchange Framework

AB 133 (Committee on Budget, Ch. 143, Stats. 2021) among other provisions, required the CHHS, along with its departments and offices and in consultation with stakeholders and local partners, to establish the DxF to include a single data sharing agreement and common set of policies and procedures that will govern and require the exchange of health information among health care entities and government agencies in California.

The DxF is not intended to be an IT system or single repository of data, but rather a technology agnostic collection of organizations that are required to share health information using national standards and a common set of policies in order to improve the health outcomes of the individuals they serve.

As part of this process, CHHS convened a stakeholder advisory group to advise on development of the DxF. This process is ongoing.

3. Including EHR vendors in the DxF

According to the author:

> The Health and Human Services Data Exchange Framework is intended to enable real-time exchange of patients' medical data between physicians and other healthcare entities to improve patient care and reduce costs within the healthcare system.
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> Unfortunately, electronic health record (EHR) vendors appear to be creating barriers to this plan by charging unreasonable fees. Healthcare providers are heavily reliant on their EHR vendors to support these requirements because it is very difficult and expensive to switch vendors. EHR vendors can take advantage of this by charging unreasonable fees, including fees as high as tens of thousands of dollars per physician for the required support.
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> SB 582 will prevent unfair practices by their EHR vendors, first, by requiring EHR vendors to be governed by the Data Sharing Agreement that will apply to all participants under the Data Exchange Framework and, second, by incorporating federal standards for reasonableness of health IT vendor fees into state statute and authorizing the state to enforce these standards. By adding this state oversight, SB 582 will ensure that unfair vendor fees do not become a barrier to successful implementation of the Framework and the gains in patient care that medical data sharing will unlock.

In response to the concerns that EHR vendors are preventing entities from smoothly and properly operating under the DxF data sharing agreement, this bill requires the stakeholder advisory group to consider whether standards for including these vendors in the DxF are appropriate and to develop such standards if determined appropriate.

If such standards are thereby developed, EHR vendors will be required to execute the DxF data sharing agreement within 12 months.

To directly address the issue of exorbitant fees being charged by EHR vendors, the bill requires fees charged by the vendors to enable compliance with the DxF to be reasonable and consistent with the Cures Act regulation discussed above, which provides guidelines for fee charging that does not constitute "information blocking." The bill authorizes CHHS, in consultation with the stakeholder advisory group or a subsequent governing board, to establish administrative oversight and enforcement authority over EHR vendors found not in compliance with these requirements. This can include the imposition of fines and penalties.

The California Medical Association, the sponsor of this bill, writes:

> To comply with both the DxF and the federal regulations, physicians are heavily reliant on their EHR vendors. For example, if a practice decides to implement the DxF by contracting with a health information organization (HIO), they will need their vendor to work with the HIO to develop an interface that facilitates the flow of data. That interface may be unique to the practice.
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> The problem arises when the vendors take advantage of situations like the one mentioned above and then charge unreasonable fees to the practice to develop the interface. These fees can range into the tens of thousands of dollars per physician. Compliance with the DxF is required in state law, physicians then face a daunting choice: pay the fees, break state law or change EHR vendors. All of the above can cause massive disruption for the practice and the patients they serve.
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> This bill addresses the issues mentioned above by empowering the Data Exchange Framework Advisory Group to develop standards for including EHR vendors in the Framework, requiring EHR vendors to sign the Data Sharing Agreement being developed by CHHS and incorporating federal standards for reasonableness of vendor fees into state statute and authorizing the state to enforce these standards.

Writing in opposition, OCHIN and the California Telehealth network argue:

> This bill creates a new California regulatory arm while borrowing only some portions of federal regulations related to the reasonableness of fees that are already enforceable under federal law. As such, this creates a duplicative state enforcement agency responsible for enforcing federal regulations. This will drive additional compliance obligations and is very likely to drive different interpretations and create greater costs. The increase in costs, as outlined above, will largely be a function of DxF provisions that are different from federal interoperability and digital data and technical standards.
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> The federal work on TEFCA is moving apace, and we are concerned this bill could undermine efforts to move interoperability forward. Interoperability is critical to support public health readiness and mitigation and sentinel capabilities in addition to research and movement to new payment models.

It should be noted that while not directly impacted by the provisions of this bill, serious privacy concerns have arisen in connection with the creation of the DxF data sharing

agreement. In their public comment, Planned Parenthood Affiliates of California illustrate some of these concerns:

> **The DxF must provide greater clarity and protection for patient data than is currently available in the Federal Information Blocking Regulations.** The Federal Information Blocking Regulations, including the applicable exceptions, do not provide sufficient clarity or protections for DxF participants who may face pressure to share personally identifying information pertaining to a person seeking, obtaining, or providing sensitive services. Across the country, state governments and private individuals continue to escalate unprecedented efforts to restrict or penalize access to essential health care services, with increasing scrutiny of contraception, abortion, mental health care, and transgender-affirming services. Planned Parenthood, as a trusted provider of sensitive health care services for millions of Californians, sees many patients who come to our health centers, including from out of state, not only because they trust Planned Parenthood to provide high-quality health care, but because they trust Planned Parenthood to protect their privacy and confidentiality. In the endeavor to facilitate information sharing, the DxF must adopt clear protections for data pertaining to sensitive services so as to avoid [weakening] or undermining California's existing protections for patients who are seeking sensitive services and who may not want their Primary Care Physician, a provider in another state, or other third-party entities to access information regarding sensitive services they received.
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> **Without stronger protections in the Privacy Standards and Security Safeguards, the DxF will undermine California's larger efforts to protect access to and confidentiality of sensitive services.** Policies and Procedures that do not include adequate safeguards against potential voluntary or compulsory disclosures of protected health information and personally identifying information, including from entities outside of California, will subsequently diminish California's protections for patient data. This is especially concerning for health care services that are increasingly stigmatized and penalized in other states, as is the case for many sensitive services, causing patients to travel from across the country to California to access private and confidential health care services. For example, the California legislature recently passed SB 107 and AB 2091 in response to other states' hostility to sensitive services. Amongst other provisions, SB 107 and AB 2091 enact data protections for services protected by the Reproductive Privacy Act as well as gender-affirming health care and gender-affirming mental health care respectively. Despite the protection of SB 107, AB 2091, and other bills passed to protect providers and patients from the hostility of other states' laws, law enforcement and private individuals in other states may seek to enact

penalties on those who receive or provide sensitive services lawfully in California.

Adequate privacy and security protections are the first line of defense against legal actions founded on another state's laws that violate California public policy. Requiring providers of sensitive services to share information through the DxF – without substantial assurance that entities who can access that information, including participants not covered by the Health Insurance Portability and Accountability Act (HIPAA), will respect patients' privacy needs – risks degrading trust between patients and providers. Regardless of existing federal law, if the DxF is to achieve its intended purpose of maintaining the privacy, security, and integrity of data and promoting trust among participants, then the DxF Policies and Procedures must provide more stringent privacy protections and assure providers that they will not risk their own patients' privacy, liberty, and safety in complying with the data sharing requirements of the DxF.

For these reasons, **PPAC respectfully requests that CalHHS consider additional protections from the increasingly hostile legal landscape that providers and patients face**, especially for sensitive services, when delineating the Policies and Procedures for the DxF pertaining to information blocking, privacy standards, and security safeguards.[1]

SUPPORT

California Medical Association (sponsor)
California Academy of Family Physicians
California Orthopedic Association
California State Association of Psychiatrists

OPPOSITION

California Telehealth Network
OCHIN

RELATED LEGISLATION

Pending Legislation: AB 1331 (Wood, 2023) requires the Center for Data Insights and Innovation to take over establishment, implementation, and all the functions related to the DxF on or before July 1, 2023, subject to an appropriation in the annual Budget Act. It requires the center to establish the CHHS Data Exchange Board, with specified

[1] Public Comment, *Re: PPAC Comments on the Draft Data Exchange Framework (DxF) Policies and Procedures* (February 14, 2022) CDII website, https://www.cdii.ca.gov/wp-content/uploads/2023/02/PPAC_Matsubara_Feb-14-2023_Comments.pdf. (Emphasis in original)

membership, to develop recommendations and to approve any modifications to the DxF data sharing agreement, among other things. AB 1331 is currently in the Assembly Health Committee.

Prior Legislation: AB 133 (Committee on Budget, Ch. 143, Stats. 2021) *See* Comment 2.

PRIOR VOTES:

Senate Health Committee (Ayes 11, Noes 0)

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