EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

350 North Orleans Street, Suite S10000
Chicago, IL 60654

@EHRAssociation | ehra.org

February 21, 2024

Secretary Mark Ghaly, MD, MPH
California Health & Human Services Agency
1215 O Street
Sacramento, CA 95814

RE: The Implementation of California Assembly Bill 352 (AB 352)

Dear Secretary Ghaly,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we seek clarification regarding the implementation of AB 352 and offer ourselves as a resource during the development of any regulatory requirements that will result from the enactment of this legislation. As the national trade association of EHR developers, Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

AB 352 creates specific requirements for businesses that store or maintain medical information for healthcare providers, among others. Association members are directly impacted as developers of health IT who serve as technology partners to virtually all physician practices and hospitals in California. Therefore, we offer our collective expertise related to the current capabilities, necessary development, and timeline considerations relevant to the development of health IT that will be critical to the successful implementation of the new law.

The EHR Association respects the intent of AB 352 and our members will seek to comply. However, the specified timeline requiring compliance by July 1, 2024, does not provide adequate time for health IT developers or other applicable businesses to develop, test, and release the expanded functional revisions within EHRs and other health IT that will be necessary to enable the requirements of 56.101(c) of the California Civil Code. Additionally, in order for our member companies to appropriately plan for and begin development to achieve compliance with AB 352, we need clarification regarding how the California Health and Human Services Agency (CalHHS) intends to implement AB 352.

The new legislative requirements included within AB 352 do not align with the current capabilities of EHRs in use in California. The EHR Association, through extensive experience in complying with

regulatory changes over many years, has determined that new capabilities requiring significant development work (such as these) require at least 18-24 months for development. Further, this necessary 18-24 month time period is from the release of the new requirement(s) inclusive of technical guidance, and once any standards necessary for that development have reached sufficient maturity for adoption.

The current timeline allows just over nine months between the enactment of AB 352 (September 27, 2023) and the required compliance date of July 1, 2024. More critically, we are currently only four months away from the deadline but have received no technical or clinical guidance yet from the state. It is not feasible for any health IT developer to develop, test, roll out, and have clients upgrade to a new version with this new required functionality, particularly given the lack of national standards relating to this type of data segmentation.

In addition to our concerns about the timeline, the EHR Association also requests additional information regarding how CalHHS generally intends to regulate the implementation of AB 352. Without additional information in the immediate future, our member companies cannot begin planning the best path to making available the functionality necessary for compliance.

For example, AB 352 mandates restrictions on access to and segmentation of certain sensitive health information related to gender-affirming care, abortion care, and contraceptive health information. While these terms may be assumed to be understood, our member companies require precise, detailed guidance when developing software in order to effectively code the software to the requirements and ensure compliance. Clarification is needed as to – very specifically – what information that would be stored in an EHR or other health IT is considered sensitive and subject to segmentation and access restrictions. Without such clarity, the capabilities created may overly restrict information or do so inconsistently from one EHR system to another, and the burden of determination will likely fall to providers. The result would conceivably include both entirely inconsistent determinations and health information exchange patterns of sensitive information across the state.

To position all stakeholders for compliance success, we suggest CalHHS consider the following actions:

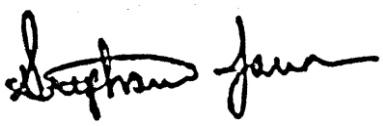
- Clearly define all key terms not outlined in AB 352 statutory language.
- Precisely specify which types of medical information require restriction (such as medications, labs or tests conducted, lab or test results, clinical notes, etc.), taking into account the current capabilities of health information technology to segment such data from a larger record to be exchanged and the lack of standards.
- Releasing specific codes (e.g., RxNorm codes, ICD-10 codes, SNOMED codes, etc.) that should be considered sensitive and restricted. As one example, the State of Maryland recently issued a list of ICD-10-CM, HCPCS, and NDC codes in COMAR 10.11.08 for the enactment of HB 812 creating restrictions on the release of certain maternal health care information.

Additional questions, concerns, and considerations from EHR Association member companies can be found below. We are hopeful that CalHHS provides this clarity, as it will be untenable for our member

companies to support California clients with their compliance without such guidance. We also ask CalHHS to provide its expected timeline for the release of these clarifications.

Thank you for your consideration, and please let us know if we can expand on any of these questions or concerns for you. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org, who in turn can help identify a time that will work for all stakeholders to schedule an online meeting.

Sincerely,



Stephanie Jamison
Chair, EHR Association
Greenway Health

William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
CPSI

HIMSS EHR Association Executive Committee

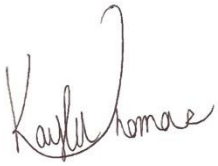
David J. Bucciferro
Foothold Technology

Leigh Burchell
Altera Digital Health

Danielle Friend
Epic

Cherie Holmes-Henry
NextGen Healthcare

Ida Mantashi
Modernizing Medicine



Kayla Thomas
Oracle Health

In this document, the EHR Association has compiled and refined questions that member companies have raised regarding the implementation of California's recent reproductive privacy legislation. We appreciate any guidance that can be offered on these questions as we look to support our California clients.

1. Is the scope of the law dependent on the provider operating under a California license, the patient's home address being in California, the provider's or patient's location at the time of service being in California, or something else?
    a. Telehealth examples: Is it in scope if a provider based in California conducts a telehealth visit with a patient located in New York? Or if a provider based in New York has a telehealth visit with a patient located in California?
    b. Multi-state organization examples: If a healthcare organization has sites in both California and other states, are they expected to filter information shared about patients exclusively seen outside of California?

2. Are sensitive health services provided outside of California in scope? If a California provider learns that sensitive health services were provided out of state, are they permitted to redisclose that information?

3. Are patient-initiated disclosures in scope? Patients can use features in the patient portal to send a copy of their record. The recipient type may not be known (e.g., a patient might email their record to another provider or a family member). Are patients permitted to disclose their own sensitive health information?

4. What sort of advance notice should healthcare organizations anticipate when the definition of sensitive health information changes?
    a. Some updates may take a few weeks (e.g., adding a new RxNorm code)
    b. Other updates may take months or years (e.g., adding new data types to be considered, such as implants).
    c. We suggest a process for soliciting feedback from the health IT community when any new updates are proposed, including the timeline that would be practical for the implementation of proposed updates.

5. Is consent expected every time a patient requests their sensitive health information be shared, or can consent apply to multiple disclosures?

6. Many EHR Association members will likely be incapable of implementing segmentation technology by July 1, 2024, due to some of the challenges noted above. Will California consider a compliance timeline extension?
    a. The scope of the project and the development required is unclear given all of the current open questions.

b. A complex project to segment data will likely take months or years to design and develop.
c. National standards for data segmentation have not reached maturity or consensus.

7. Providing new features, such as data segmentation capabilities, will require healthcare organizations to upgrade their EHRs. EHR developers do not control the upgrade timelines of their clients. How should EHR developers approach situations in which customers choose not to upgrade?

8. Protecting patient privacy will require certain actions on the part of California healthcare providers, such as labeling sensitive data, configuring their system in certain ways, and using certain workflows. EHR developers cannot control system configuration and usage by healthcare providers. How should EHR developers approach situations where their customer chooses not to configure or use the system to restrict disclosure of sensitive health information?

9. EHR developers do not have direct relationships with patients and do not disclose patient information or collect consent from patients; disclosures of information and consent management are done by healthcare providers.