

April 5, 2023

Attn: The Honorable Susan Talamantes Eggman
Chair, Senate Health Committee
1021 O Street
Sacramento, CA 95814

RE: Senate Bill 582 - Oppose Unless Amended

Dear Chair Eggman,

The HIMSS Electronic Health Record (EHR) Association is pleased to have the opportunity to provide feedback to the California Senate Health Committee and to Senator Becker on Senate Bill 582.

As a national trade association of EHR developers, EHR 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.

We support the overall intent of the Data Exchange Framework and our members are working to enable compliance with its requirements by our clients. However, we do have four specific points we would like to submit for the Committee's consideration.

1. We do not believe this proposed legislation is necessary to require the compliance of certified EHR technology or other health IT developers since these developers are business associates of the participants already required to participate in the Data Exchange Framework.

As business associates, we are contractually obligated to share certain health data when requested by our clients, and in some cases, when requested by others on behalf of our clients. The language of SB 582 would only reiterate the requirements already in place for us as health IT developers, both contractually and under federal information blocking regulations. If the intent of SB 582 is to focus on health IT developers that are not already bound by these obligations, that intent should be made clear in the bill.

AdvancedMD	CureMD	Experity	MEDITECH, Inc.	Oracle Cerner
Allscripts	eClinicalWorks	Flatiron Health	Modernizing Medicine	Sevocity
Altera Digital Health	Elekta	Foothold Technology	Netsmart	STI Computer Services
Athenahealth	eMDs – CompuGroup Medical	Greenway Health	Nextech	TenEleven Group
BestNotes	EndoSoft	MatrixCare	NextGen Healthcare	Varian – A Siemens Healthineers Company
CPSI	Epic	MEDHOST	Office Practicum	

2. We are concerned with how the term “EHR vendor” is currently drafted in SB 582, including how the term “EHR vendor” is defined in the bill and the use of language referencing the federal fees exception compliance requirements under the information blocking regulations at 45 CFR 171.302(a). We have outlined these concerns below.

- The definition of “EHR vendor” as drafted in SB 582 is vague and is unique to the California Data Exchange Framework concept. Many participants and their business associates under the Data Exchange Framework operate in states beyond California. Unique definitions in each state create compliance burdens for participants, whereas federal definitions enable alignment and ease burden on providers and health IT suppliers alike.
- The EHR Association suggests the use of the federally defined term “Health Information Technology” as defined at 42 USC 300jj. This definition creates alignment between California and federal requirements and allows the Data Exchange Framework terminology to cover health IT beyond certified EHR technology – if that is a goal of this bill.

3. We have several concerns regarding the draft language of SB 582 that incorporates the federal Fees Exception to the information blocking compliance regulations into the California Data Exchange Framework. The language of SB 582 only incorporates the Fees Exception at 45 CFR 171.302(a) into the California Data Exchange Framework and does not incorporate the Content and Manner Exception (45 CFR 171.301) or the Licensing Exception (45 CFR 171.303). These three exceptions work together to form a set of reasonable and necessary business practices under the information blocking regulations based upon procedures that can be used to meet requests for access, exchange, or use of Electronic Health Information (EHI) without violating the definition of information blocking. The three exceptions must work together, and cannot be separated for the following reasons:

- The Content and Manner Exception provides for instances when information blocking requirements may apply by defining a scope of information as well as outlining the manner in which it is provided. Additionally, the Content and Manner Exception provides for scenarios in which the Fees and Licensing Exceptions apply and when they do not. Specifically, the Content and Manner Exception allows actors under the information blocking regulations to comply with those requirements without meeting the Fees and Licensing Exceptions in certain instances.

To remove this ability for actors under the information blocking requirements within the State of California would be removing a protection specifically designed by the Office of the National Coordinator for Health IT (ONC) that has been deemed as a reasonable and necessary business practice.

- The Licensing Exception is also a necessary inclusion as it dictates contractual terms that may be included and royalties that may be charged when contracting for the use of

“interoperability elements” as defined at 45 CFR 171.102. The term interoperability elements would likely include some of the functionality necessary for participants to exchange information under the Data Exchange Framework and therefore ensuring the terms of the Licensing Exception is also necessary.

4. Finally, the EHR Association is concerned that SB 582 grants additional enforcement authority to the California Health and Human Services Agency (CalHHS) by authorizing it to review complaints and impose fines and penalties against EHR developers that CalHHS determines are not in compliance with the Fees Exception at 45 CFR 171.302(a), possibly resulting in inconsistent application and enforcement. Developers of certified health IT are actors under the information blocking regulations and are therefore already subject to review and penalty by the Office of Inspector General (OIG). Additionally, health IT developers that are certified are subject to the conditions and maintenance of certification requirements of ONC that include attestation of compliance with the information blocking regulations and are subject to review and penalty by ONC for false attestations or violation of the conditions and maintenance of certification requirements.

For health IT developers that are already subject to these requirements and federal review and imposition of penalties, the language of SB 582 would create a third method through which these developers could be penalized. This too is likely to result in inconsistent application of the policy and excessive penalties. Additionally, if other states were to follow this example there would be potential for 52 separate reviews and penalties for similar actions across the country.

We believe that those health IT developers already subject to the conditions and maintenance of certification requirements and the information blocking requirements should be excluded from additional review and imposition of penalty by CalHHS. CalHHS can turn any potential complaints against these entities over to ONC and OIG for their own review and imposition of penalties.

Thank you for your consideration and please let us know if we can expand on any of these concerns for you. The Association’s leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org.

Sincerely,

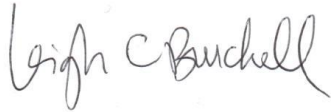


David J. Bucciferro
Chair, EHR Association
Foothold Technology

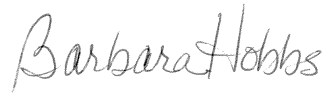


William J. Hayes, M.D., M.B.A.
Vice Chair, EHR Association
CPSI

HIMSS EHR Association Executive Committee



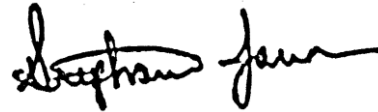
Leigh Burchell
Altera Digital Health



Barbara Hobbs
MEDITECH, Inc.



Cherie Holmes-Henry
NextGen Healthcare



Stephanie Jamison
Greenway Health



Ida Mantashi
Modernizing Medicine



Kayla Thomas
Oracle Cerner

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.