EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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December 21, 2022

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

Dear Secretary Ghaly,

On behalf of the 30 member companies of the HIMSS Electronic Health Record (EHR) Association, we thank the California Health & Human Services Agency (CalHHS) for publishing the Data Exchange Framework, Single Data Sharing Agreement, and related policies and procedures.

As a national trade association of EHR developers, our 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.

The electronic exchange of health information is a consistent focus of the EHR Association, and we appreciate learning that others share our focus and regard for the topic. We believe the collective knowledge and expertise in the field of health IT interoperability amongst our Association members could be valuable to you in constructing the Data Exchange Framework and further expanding the exchange of health information.

To that end, we have compiled some of our thoughts on the current Data Sharing Agreement (DSA) and its related policies and procedures (the DSA and related policies and procedures will be referred to as the 'DEF' as part of the overall Date Exchange Framework for the purposes of this letter). In some areas, we are simply asking for clarification, which may include the addition of clarifying language into the DSA and related policies and procedures themselves. In other areas, we are voicing our concern about how the DSA and related policies and procedures are to be implemented in the context of Federal requirements.

There are a few areas outlined in the DEF which require additional clarity. These terms are generally defined in the DEF; however, the actual requirements remain ambiguous. The main areas in need of clarity are the scope of data expected to be exchanged under the DEF, the standards expected to be

used in the exchange of data under the DEF, the timing of the exchange of data under the DEF, and the entities capable of performing the exchange of data under the DEF. We will expand on each of these below.

Data to be Exchanged

The Data Elements to be Exchanged Policy and Procedure define the data to be exchanged by healthcare providers, after October 6, 2022, as "all Electronic Health Information (EHI) as defined" at 45 CFR 171.102, "including data elements in the United States Core Data for Interoperability (USCDI) Version 2, if maintained by the entity." Other entities participating in the DEF have separately defined scopes of data that in some cases mirror the requirements for healthcare providers and in other cases include seemingly significantly fewer sets of data.

While the definition of EHI seems clear enough, there is actually quite a bit of discussion within the healthcare industry as to the exact scope of EHI. This can be demonstrated in the efforts undertaken by the American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), and the EHR Association in a joint report issued in August 2022, titled *Defining EHI and the Designated Record Set in an Electronic World*. This was also addressed by the Information Blocking Compliance Workgroup under the Interoperability Matters public-private collaborative created by The Sequoia Project, which also published guidance on understanding and operationalizing EHI.

While the reports speak for themselves, both indicate consensus around certain aspects of the designated record set and EHI definition, but there are several areas that are likely unique to individual participants and healthcare providers. This makes EHI a particularly challenging scope of information to operationalize at scale and to ensure stakeholders understand which data may be expected to be shared or not. One of the documents released by the Information Blocking Compliance Workgroup is an infographic demonstrating how EHI lives in multiple health IT products/systems across nearly all healthcare providers, as well as how it would be unrealistic to provide singular exchanges of all EHI maintained by a healthcare provider for all requests at this point in time.

While the concept of EHI, as used in the information blocking regulations, is part of an obligation to ensure sharing of information when requested without any associated standards, formats, or timing requirements, the DEF takes the same concept of EHI and attempts to apply strict timing, standards, and formatting requirements to the concept. This will lead to confusion and the risk of inadvertent compliance violations.

We ask CalHHS to consider leaving EHI as the outside scoping of data that can be requested and instead set more granular data scoping requirements for the real-time exchange expected to occur under the DEF. This approach is similar to how exchange will work under the Trusted Exchange Framework and Common Agreement (TEFCA), as it sets a large scope of information that can be requested (Required Information) but also establishes a minimum data set and formatting standard. The Qualified Health Information Network (QHIN) Technical Framework (QTF) of USCDI v1 requires the use of a template from the HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes – US Realm. TEFCA also outlines how the dataset, formatting, and exchange standards can all be updated in the future, including a roadmap for moving to Fast Healthcare Interoperability Resources (FHIR®) over a few years. By also taking this approach, CalHHS could set smaller sets of data expected to be exchanged

in real-time, while allowing requestors to ask for additional information beyond those datasets with additional time built in to allow the responding participant time to gather the information for the response.

Standards

The scope of data to be exchanged when a request is made under the DEF is impacted by several factors – one of which seems to be the Data Standards and Data Formats sections (sections 2 and 3) of the Data Elements to be Exchanged Policy and Procedure. The Data Standards section indicates participants in the DEF shall use standardized data element formats and code sets in the exchange of health information under the DEF. The standards referenced call out the code sets and terminologies identified in USCDI v2 and then point to the Standards Version Advancement Process (SVAP) for data elements beyond USCDI v2. However, the SVAP process does not outline code sets, terminologies, or standards for all of the data elements necessary to meet the definition of EHI. The SVAP process is not intended to encapsulate the definition of EHI – It is a voluntary process through which health IT developers seeking to certify their software for use by their clients can *voluntarily* certify to updated standards for those certification criteria as updated standards are released. It does not include any standards associated with claims data or financial data at this point in time. SVAP is completely voluntary and not mandated for adherence by health IT developers.

We are concerned about CA's reference to USCDI v2 as the floor, as ONC's 21st Century Cures update to the 2015 Certification rules indicates USCDI v1 as the floor; it allows for the adoption of USCDI v2 through the SVAP process but does not require the SVAP process. We strongly urge CalHHS to follow the same approach to enable predictable and consistent adoption of standards-based interoperability. Where data exchange is pursued beyond the necessary standards to support USCDI v1, we suggest that CA DEF references ONC's SVAP that participants in CA DEF should adopt. Data exchange beyond the most current standards supporting the then most current USCDI version, including what is outlined in SVAP, should be pursued in collaboration with the SDOs to enable the adoption of the most likely and prudent standards, as will be published over time. This would align, to some extent, with the content and manner exception from ONC's information blocking regulations, in allowing the use of SDO-published standards. We encourage CalHHS to allow formats agreed to by both parties even if those formats differ from the noted standards.

Timing

An additional area needing clarity is the meaning of "real-time exchange" under the DEF. While this term is used in the DSA, it is never defined. It is used to describe the requirement to exchange health and social services information, but no specific timeframes are given. The reader/participant is directed to the timeframes contained in the policies and procedures, but there are also no specific timeframes given in the policies and procedures, except that the Requirement to Exchange Health and Social Services Information Policy and Procedure states a participant shall respond "as soon as reasonably practicable, but in any case, within the timeframes required by Applicable Law."

We strongly suggest that the term "real-time exchange" should be defined or timeframes for exchange should be clearly stated within the DEF. We encourage CalHHS to consider that what constitutes a reasonable timeframe for the exchange of health information may differ depending on the request. For example, a request for a population-level dataset will generally take longer to fulfill than a request for a

single patient's encounter-based information contained in a C-CDA document. We suggest that CalHHS note that the real-time exchange terminology may differ depending on the request type and capabilities available to the requestee.

Penalties/Disincentives for non-compliance

The potential repercussions for healthcare organizations that do not enter the DSA by January 31, 2023, or do not exchange information by their respective deadline is another area that needs clarification. The legislation codified in CA Health and Safety code 130290 does not specify any penalties or disincentives and the DSA and related policies and procedures also do not provide any indication of potential penalties or disincentives. We do note that the legislation and website outline $50 million that has been set aside as grants to incentivize the program, and we support the use of incentives over penalties. However, we have received many questions from our clients when discussing the DEF as to the potential penalties. This is an area for which clarification could seemingly be quickly addressed through an FAQ or additional documentation.

Exchange Capabilities

Finally, we suggest that CalHHS provide clarity regarding how information can be exchanged. While we are seeking clarification in several areas, the DEF does outline what data should be exchanged, which standards should be used, and for what purposes the data should be exchanged; however, the DEF does not provide any guidance as to the methods through which the data is to be exchanged. There is discussion in the DEF on the exchange being technologically agnostic, as well as participants being able to use their own functionality or contract with Qualified Health Information Organizations (Qualified HIOs) to perform the exchange. The DSA mentions there will be state-designated Qualified HIOs, however, we are not aware of a list being published at this time. We believe additional clarity is needed for potential participants and their technology partners to understand exactly what capabilities will be necessary to meet the requirements for exchange on January 31, 2024.

Generally, we believe meeting the requirements outlined in the DEF will likely take additional time, as there are many areas still lacking clarity that may determine what capabilities are necessary for compliance and whether additional development beyond that which is necessary to support ONC's Certification Program and connections through TEF and/or Carequality will be required. The EHR Association has traditionally put forth a stance that the minimum amount of time between the release of new requirements specific to health IT functionality and the date on which those capabilities will be available for use by provider organizations should be at least eighteen months from the release of <u>all</u> necessary technical specifications. The DEF was released on July 1, 2022. Participants are expected to sign the DSA by January 31, 2023, and yet there are still many unknowns as to exactly what participants are agreeing to in the contract. Additionally, exchange is expected to begin for most participants on January 31, 2024, which is only fourteen months away.

Depending on when the necessary clarifications outlined in this letter are made available and which standards will be required, we encourage CalHHS to provide at least eighteen months from that date until exchange is expected to begin. We would also encourage CalHHS to allow participants to wait to enter the DSA until all policies, procedures, and necessary clarifications are released.

Thank you for this opportunity to share our experiences and expertise. We appreciate the collaboration to leverage health IT and to enable interoperability for clinicians and the patients they serve and welcome the opportunity for further discussions. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org.

Sincerely,

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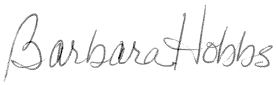

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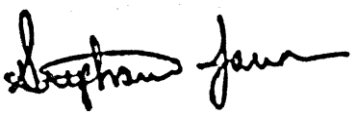

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Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that 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.

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