February 14, 2023

John Ohanian
Chief Data Officer
California Health and Human Services Agency
1205 O Street
Sacramento, CA 95814

Subject: Feedback on draft Policies and Procedures

Dear John:

On behalf of Sutter Health, thank you for the opportunity to submit comments on the Cal HHS's draft policies and procedures for California's Data Exchange Framework (DxF).

Sutter Health is an integrated, not-for-profit health care delivery system that spans across 22 counties in Northern California, with 24 hospitals, more than 50,000 employees and over 5,000 affiliated physicians. We serve more than 3.4 million patients – nearly 1 percent of the U.S. population, in one of the most diverse and innovative regions in the world. Sutter Health was an early adopter of health data exchange, and we are committed to working with the state to ensure proper data sharing of patient data. However, given Sutter's commitment to efficient, well-coordinated and high-quality patient-centered care for everyone who lives in the communities we serve, we have significant concerns with the current policies and procedures as they are currently drafted.

We strongly encourage the state to consider more closely aligning the California DxF Policies and Procedures to the existing regulations found in the Federal information blocking and TEFCA rules. The Policies and Procedures deviate in significant ways from frameworks that already require significant resources to comply. The currently proposed Policies and Procedures lack the specificity needed to implement and envision broad exchange use cases that are not supported by any current technology. Sutter has long supported health data exchange. Sutter signed the Data Sharing Agreement by the January deadline to support our shared vision of data exchange improving individual and public health, but we are worried about the viability of the proposed Policies and Procedures. We would suggest narrowing the use cases (decrease HSSI to USCDI V1 to start for example). The expansion of the Federal laws from EHI to HSSI without ensuring there are agreed upon standards for how HSSI is defined will make it near impossible for health providers to comply. Additionally, we would suggest slowing the implementation to assure feasibility and we would suggest consulting more closely with the vendors who are responsible for building the tools needed to implement these rules to ensure viability.

1) California Information Blocking Prohibitions
    a) Sutter Health believes the state data exchange framework should align with the Federal information sharing regulations and allow for a fee exception. There should be similar restrictions on fee setting as the Federal regulations to ensure health systems are not forced into paying exorbitant fees with no ability to decline given the requirements under the law and the policies and procedures to partner with a QHIO.
2) Technical Requirements for Exchange

a) Broadcast queries can place significant strain on IT architecture of provider organizations and should be only used in narrow use cases. The Policies and Procedures need to be more specific on how broadcast queries can be done responsibly if they continue to permit them.
b) We do not believe that it is appropriate to require Participants to receive HSSI via direct messaging. Direct directories are often unreliable and such transmissions may not reach the intended recipient and depending on their structure may not allow appropriate data parsing for digestion by humans or data tools. Additionally, clinical end-users are already inundated with messages in their inbaskets/inboxes and expanding the use of direct messaging may lead to further provider burden. Lastly, it would unnecessarily expand the data sets that providers are required to maintain under Federal law by pushing data that is unrelated to individuals' care with a provider into said provider's EMR.
c) Until we further narrow the use cases and type of data exchanged the standard or method of exchange is less critical. HIE is the industry standard for "pulling" health data from another system and direct secure messaging is often more appropriate for "pushing" HSSI. As most healthcare entities will be both recipients and senders we recommend that any burden to support exchange standards be placed on the participant delivering HSSI.
d) In III.3.a.i.b "Participant Hospitals are required to send electronic Notifications of ADT Events to at least one Qualified HIO" but it remains unclear what the requirements are to become a QHIO or how many will become "qualified" and if a health system needs to match geography with a chosen QHIO. Sending all of our ADT info to a single organization without clear understanding of how that organization will be selected and governed makes us hesitant as stewards of our patients' data. It is unclear from the Policies and Procedures how a participating organization would be able to subscribe to the ADT events for the patients in whom it is interested and has an appropriate relationship. Having a clear design of how such a system would work is critical to roll out before we roll out a requirement to participate.

3) Real-Time Exchange
a) III.1.a.i "In response to an Order for services or a Request for Services, Participant(s) must share the Health and Social Services Information associated with the Order or the Request for Services without delay."

   Order for services is a broad term that is not defined within the Policies and Procedures that could mean anything from a medical referral to a social services request to a lab or imaging order to a DME supplies order. There is currently no standard in place to do this type of order and response model either between same vendor health providers or between different vendor systems. This item should be better defined and narrowed to use cases that have demonstrated technical viability and an agreed upon standard of exchange.

4) Early Exchange
a) We believe that any requirement exceptions for early exchange are premature given the problems in the rest of the Policies and Procedures outlined in answers to other questions. However, as the regulations allow for early exchange, there should be significant latitude afforded to early adopters who volunteer to exchange data. Allowances should be made for both the scope of the data exchanged and adherence to technical requirements.

5) Privacy Standards and Security Safeguards
a) The notification requirement in this section is not aligned with HIPAA or CDPH reporting requirements. Both HIPAA and CDPH frameworks allow a risk assessment with potential

mitigation. Section C appears to require notification even if an errant disclosure is mitigated by a secure destruction and nonproliferation of data. The burden should not be shifted from the sending Participant to the receiving Participant to address the other party's inappropriate sharing of data. We strongly encourage that this section be aligned with existing statutory notification requirements.

Again, thank you for the opportunity to comment on these draft policies and procedures. We look forward to working with you and your team as you continue to develop the state's DxF. If you have any specific questions, please don't hesitate to contact me, or Sutter Health's Director of Government Affairs Joe Gregorich at joseph.gregorich@sutterhealth.org

Sincerely,

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