April 29, 2022

John Ohanian
Chief Data Officer
Director, Center for Data Insights and Innovation
California Health and Human Services Agency (CalHHS)

Re: Suggested edits and additions to the draft Data Sharing Agreement (DSA) and related Policies

Dear John:

Please find below Manifest MedEx's (MX's) comments and recommended edits on the DSA and related Policies. We urge California Health and Human Services Agency (CalHHS) to address these issues to ensure meaningful and effective data sharing by payers, providers, hospitals, social service organizations and public health systems to support California's ambitious health goals. Thank you for the opportunity to provide input.

Recommended Edits

MX recommends the following edits to the DSA and Policies

Document/Page	Recommended Edits	Rationale
Data Sharing Agreement (DSA) Definitions: p. 3 Section 7: p. 5 Policies: add "Minimum Requirements" in appropriate section Policies: add "Process for entities to designate Qualified HIOs" in an appropriate place	**Add this to Definitions section:** **"Qualified Health Information Organizations 'Qualified HIOs'** shall refer to data exchange intermediaries approved by the California Health and Human Services Agency (CalHHS) to facilitate data exchange between Participants. CalHHS shall establish a rigorous process to evaluate and approve Qualified HIOs, using the following baseline requirements: • Status as a non-profit organization or local government agency based in California • Openness to participation by any provider or health plan in their service region • The ability to faciliate data exchange between Participants for all Required Purposes and using all Standards set forth in the DSA, within timeframes established by CalHHS Qualified HIOs shall sign the DSA (becoming Participants) and meet its terms and conditions, as well as be subject to all Policies and Procedures associated with the DSA, and to	California's HIOs form the core infrastructure for a successful DxF that equitably meets state goals, as seen in other large states such as New York and Michigan. Our HIOs serve diverse communities of providers, linking community health centers and small practices with commercial payers and health systems. They share a history of not only meeting local needs, but of responding to and advancing state data exchange initiatives in California – including public health COVID response, the Cal-HOP program, EMSA initiatives and CalAIM. In contrast, other types of organizations seemingly being considered as "data sharing intermediaries" for the DxF do not align with key DxF principles that stakeholders would expect of the state. For instance, for-profit software vendors do not possess the transparent governance or public

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	any special amendments to the DSA specific to Qualified HIOs as determined by CalHHS. Qualified HIOs shall exchange data with each other to create a statewide data exchange network, in a manner and timeframe to be determined by CalHHS. **Edit Section 7 as follows:** "Each Participant shall engage in the exchange of Health and Social Services Information for at least all Required Purposes as set forth in the Policies and Procedures~~.~~ either through execution of an agreement with a Qualified HIO ~~an entity that provides data exchange~~ or through use of their own technology. **Add "Minimum Requirements" language to Policies in appropriate section.** "If Participants elect to use their own technology for data exchange, rather than joining a Qualified HIO, they must meet below Minimum Requirements so that exchange is efficient and scalable: • Hospitals shall be required to proactively share ADT notifications and discharge summaries with all Qualified HIOs by establishing HL7 V2 ADT feeds and HL7 V2 ORU feeds (sharing lab data and discharge summaries) with each of these entities; • Providers and hospitals shall be required to share CDAs through eHealth Exchange or Carequality in response to queries from Qualified HIOs for any Required Purpose; • Health plans shall be required to share claims with Qualified HIOs through flat files, or designated formats, for any Required Purpose." **Add "Process for Entities to Designate Qualified HIOs" to Policies in appropriate section.** "Entities covered by AB 133 (see Division 109.7, Subdivision F) shall be required to report if they have selected a Qualified HIO as their data	service orientation required for public trust in this pivotal role. Second, national networks such as Carequality and eHealthExchange follow their own governance processes, with no clear mechanism to address state concerns or priorities. Furthermore, these networks do not support the full set of Required Purposes contemplated for the DxF, and their successful participants in California today are highly concentrated among large health systems with the internal resources to smooth out the clunky and challenging user workflows that render these networks unworkable for many smaller organizations. In short, putting California's HIOs at the heart of the DxF aligns with all of the principles established by the Stakeholder Advisory Group, whereas failing to do so makes a continued digital divide in the state's health care system the most likely outcome.

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	sharing partner when they sign the DSA by the statutory deadlines. These reports will populate a public listing of which entities have selected which Qualified HIOs. This reporting is needed so that information requesters can route requests appropriately. An entity that has selected a Qualified HIO and reported that selection using the established process, shall not be required to respond to direct requests for information from other entities."	
Policy - Data Elements to be Exchanged Page: 1	**Edit as follows:** "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, except that health plans are not required to share financial information about a given encounter with providers that did not deliver the service."	Health plans should not be required to share financial information about a given encounter with providers that did not deliver the service.
Policy - Data Elements to be Exchanged Page: NA	**Add a section to the Policy titled "Timeliness of Data Sharing" to include this language:** "The following data shall be proactively shared in real-time as available: • Hospitals: Shall share ADT alerts with patients' primary care providers and health plans, or with their selected Qualified HIOs • Hospitals and Providers: Shall report public health data pursuant to state requirements • Hospitals: Shall share discharge summaries with patients' primary care providers and health plans, or with their selected Qualified HIOs"	Participants should be required to share data proactively and in real-time, not just in response to queries, in specific circumstances where timely and proactive data sharing is needed to support care coordination and public health. For instance, a patient's primary care provider and health plan must be notified by a hospital when the patient/member is admitted or discharged. Without this notification the provider and plan cannot follow up in a timely manner to provide needed support and care coordination. Requiring proactive data sharing in at least these circumstances is required

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		to comply with the expectations outlined in AB 133: "The California Health and Human Services Data Exchange Framework will be designed to enable and require real-time access to, or exchange of, health information among health care providers and payers…"
Policy – Required and Permitted Purposes Page: 2	**Edit as follows:** " 'Health Care Operations' shall have the same meeting as set forth at ~~for purposes of this policy, shall consist of the following activities:1. Quality Assessment and Improvement activities as described in subsection (1) of the definition of health care operations set forth at~~ 45 C.F.R. Part 164.501 of the HIPAA Regulations. ~~2. Population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives as set forth at 45 C.F.R. § 164.501.~~"	Selecting only a subset of HIPAA-defined operations as required exchange purposes does not align with HIPAA, Information Blocking or TEFCA. Alignment with federal policies is required by AB 133: "The California Health and Human Services Data Exchange Framework shall align with state and federal data requirements, including the federal Health Insurance Portability and Accountability Act of 1996… and other applicable state and federal privacy laws related to the sharing of data among and between providers, payers, and the government" The DSA should require exchange for all operations purposes defined in HIPAA.
Policy – Requirement to Exchange Health and Social Services Information Page: 1	**Edit as follows:** "All Participants shall have a duty to respond to requests for Health and Social Services Information, and a duty to proactively share this information where required, for all Required Purposes. In addition, all Participants that request Health and Social Services Information for Permitted Purposes ~~or Required Purposes~~ shall have a corresponding reciprocal duty to respond to requests for Health and Social Services Information for these purposes.	All Participants should have a duty to respond for all Required Purposes, regardless of whether they are requesting information. Entities covered by AB 133 should not be permitted to charge fees for responding to queries for information from Participants for Required Purposes. That would be wholly inconsistent with the intent of AB 133.

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	A Participant shall fulfill its duty to respond by either (i) directly providing, or having its designated Qualified HIO provide, the requested Health and Social Services Information, or (ii) directly responding, or having its designated Qualified HIO respond with a standardized response that indicates the Health and Social Services Information is not available or cannot be exchanged. All responses to requests for Health and Social Services Information shall comply with Specifications, the Data Sharing Agreement (the "DSA"), any other data exchange agreements, and Applicable Law. Entities covered by AB 133 (see Division 109.7, Subdivision F) shall not charge a fee for responding to requests for Health and Social Services Information from other Participants for Required Purposes. This does not prohibit entities from paying fees to the Qualified HIOs they have selected to help them meet their own data sharing obligations."	
New Policy needed on enforcement	**Add new Policy addressing Enforcement** A critical item that is missing in the DSA and Policies is a credible compliance and enforcement approach to ensure that organizations covered by AB 133 (see Division 109.7, Subdivision F) share data for Required Purposes as mandated by AB 133 and the DSA. This should include naming the entity that will be performing enforcement oversight, providing sufficient resources to this organization, identifying the processes to both regularly review entities' compliance and receive and investigate reported violations, clearly defining what it means to comply, and establishing the consequences and penalties for organizations that do not comply. These activities are both policy and operational in nature and should not be delegated to a governance entity. If CalHHS does not yet have sufficient authority and resources to perform these functions, it	As seen from the federal Information Blocking experience, where lack of enforcement is substantially hampering impact, policies outlined in statute and regulation need to be backed up with meaningful and timely enforcement.

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	should pursue needed authorities and resources as soon as possible through legislation. This work is urgent as it is unclear that organizations required to sign the DSA under AB 133 will be willing to do so before the enforcement approach and details have been established. The Policies shared to date describe the process for overseeing and updating the DSA and Policies but do not outline the enforcement approach to ensure that entities covered by AB 133 share data as required by the law and the DSA.	
Policy – Breach Notification Page: 1	**Edit as follows:** Delete all text in section III (1) "Obligations of Participant" Replace with: Each Participant shall be expected to follow the timelines and processes for breach notification in whatever law and policies they are subject to.	As discussed in the DSA Subcommittee this week, the DSA should not impose new and divergent breach notification timelines and processes.
DSA Various mentions of "Governance Entity"	We strongly recommend that the following functions remain the direct responsibility of CalHHS, informed by stakeholder advisory committees, and not be delegated to an appointed governance entity such as the Policy Board described in recent Advisory Group meetings: • Drafting and finalizing regulations • Establishing specific standards or requirements for data sharing • Drafting and revising Policies • Enforcement with respect to whether entities covered by AB 133 comply with data sharing requirements Instead, the Policy Board should be charged with high level policy direction and assessing whether the data sharing goals established in AB 133 are being met	Functions like issuing regulations and conducting enforcement are inherently governmental and require staff, resources, government authority and other infrastructure housed within government

Finally, we concur with the conclusions of the DSA Subcommittee in their discussion this week:

- Participants should be given at least 180 days to implement changes to Policies with leeway to lengthen this time-period if needed.
- Additional clarification and limitations on liability between participations are required.

But we disagree with the view of some people in that group that HIPAA privacy and security standards should be required of all DSA signers. In our view that is an overreach. Instead, each entity should be subject to whatever policies and laws apply to their type of organization.

Additional Considerations

While outside the scope of the DSA itself, it is very clear that additional policy alignment, infrastructure and funding is needed to deliver on the AB 133 goals, including:

- Alignment of state law with federal policy to reduce the complexity and challenges of sharing behavioral health and substance use treatment data
- Registry of electronic endpoints such as Direct addresses for all Participants
- Record locator service so that Participants know where to query for patient information
- In cases where patient authorization is needed:
    - Standardized form for obtaining patient authorization
    - Electronic consent registry

Finally, it is imperative that California provide sustainable public funding to support the critical data infrastructure provided by our state's HIOs. MX has joined the EQUITY coalition of more than 20 provider, health plan, and health information organizations requesting $95 million in 2022-23, and ongoing funding after, for data sharing incentives and HIO data infrastructure. We hope the Governor's May Revision includes this funding which is urgently needed to support California's goals of improving equity and transforming Medi-Cal through whole person care.

Sincerely,

Claudia Williams
Chief Executive Officer
Manifest MedEx