

June 1, 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 to support California's ambitious health goals.

Many of our comments focus on the need to define and fund Qualified Health Information Organizations (HIOs) and assure data sharing with them. We recommend that CalHHS:

- **Establish the process and requirements for qualifying Health Information Organizations by July 2022.** It is critical to identify QHIOs as soon as possible so that entities intending to meet their obligations by joining a QHIO can select a QHIO as their partner and execute an agreement with that QHIO well in advance of the deadlines.
- **Provide public funding for Qualified HIOs.** 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 25 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 Final Budget passed by the Governor includes this funding which is urgently needed to support California's goals of improving equity and transforming Medi-Cal through whole person care.
- **Establish data sharing requirements for Participants that decline to join a Qualified HIO.** These "Minimum Requirements" will ensure that providers and health plans relying on our state's Qualified HIOs have access to the full and complete patient records needed for whole person care.

## Recommended Edits

MX recommends the following edits to the DSA, Policies, and Other Documents

Issue #	Topic	Document	Recommended Edits	Rationale
1	Process to designate Qualified Health Information Organizations (QHIOs)	New policy needed	<p>We strongly recommend that CalHHS establish the process to designate QHIOs, including the requirements QHIOs must meet, by July 2022.</p> <p>We recommend these requirements include:</p> <ul style="list-style-type: none"> <li>• Status as a non-profit organization or local government agency based in California</li> <li>• Openness to participation by any provider or health plan in their service region</li> <li>• The ability to facilitate data exchange between Participants for all Required Purposes</li> <li>• Participation in eHealth Exchange or Carequality</li> </ul> <p>Obligations of QHIOs should include:</p> <ul style="list-style-type: none"> <li>• Sign the DSA (becoming Participants) and meet its terms and conditions</li> <li>• Exchange data with other QHIOs to create a statewide data exchange network</li> </ul> <p>In addition, entities meeting their data sharing obligations by executing an agreement with a QHIO should be required to publicly document this selection using a process CHHS identifies.</p>	<p>It is critical to identify QHIOs as soon as possible so that entities intending to meet their obligations by joining a QHIO can select a QHIO as their partner and execute an agreement with that QHIO well in advance of the deadlines.</p>
2	Minimum data sharing requirements	New section needed in DSA	<p>Add this language</p> <p><b>“Minimum Requirements:</b></p> <p><b>If Participants elect to use their own selected technology or network rather than joining a Qualified HIO (QHIO), they must meet the following Minimum Requirements so that exchange is efficient and scalable:</b></p> <ul style="list-style-type: none"> <li>• <b>Hospitals shall be required to proactively share all ADT notifications and discharge summaries with at least one QHIO by establishing HL7 V2 data feeds;</b></li> <li>• <b>Providers and hospitals shall be required to share CCDAs through eHealth Exchange or Carequality in response to</b></li> </ul>	<p>As recognized in the DSA, health information organizations (HIOs) are the backbone of data sharing in California, connecting, cleaning and aggregating records to support provider and health plan care coordination, population health, and quality improvement.</p> <p>The DSA establishes that providers are not required to join and pay fees to a QHIO. But if they don’t, they should still be required to share data with QHIOs in an efficient, viable, predictable, and scalable</p>

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			<p>queries from Qualified HIOs for any Required Purpose;</p> <ul style="list-style-type: none"> <li>Health plans shall be required to share claims with at least one QHIO through flat files, or other designated formats.”</li> </ul>	<p>manner. These obligations must be clear and not subject to negotiation.</p> <p>Murkiness or lack of specificity about this obligation will perpetuate the gaps in data sharing that prompted AB 133 in the first place.</p> <p>We also agree with provider organizations like Sutter and Kaiser Permanente that the existing national networks (Carequality and eHealth Exchange) are an effective and efficient way to accomplish the query portion of this goal, but need to be paired with mechanisms for sharing claims and ADTs/discharge summaries.</p> <p>TEFCA is not a viable option to support query exchange as it is not yet fully launched and is based on network-to-network exchange.</p>
3	Enforcement	New Policy needed	<p>The DSA and Policies must include a credible compliance and enforcement approach. This should include:</p> <ul style="list-style-type: none"> <li>Naming the governmental entity that will be performing enforcement oversight and providing sufficient resources to this entity</li> <li>Clearly defining what it means for organizations to comply with the Data Sharing Framework, including signing the DSA and responding to requests for data</li> <li>Establishing the consequences and penalties for organizations that do not comply</li> <li>Regularly reviewing organizations’ compliance</li> <li>Receiving and investigating reported violations</li> </ul> <p>These enforcement activities are both policy and operational in nature and should not be delegated to a non-governmental entity.</p>	<p>Establishing the enforcement policies and approach is urgent. It is unlikely that all organizations required to sign the DSA will be willing to do so before the enforcement approach and details have been established.</p>

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4	Proactive data sharing	Policy – Data Elements to be Exchanged	Add following as a new section in this Policy: <b>Proactive Data Sharing</b> The following data shall be proactively shared by hospitals in real-time as available: <ul style="list-style-type: none"> <li>Hospitals shall share a complete feed of all ADT alerts and discharge summaries with at least one QHIO, and will also share these data directly with any primary care provider and health plan that has not selected a QHIO.</li> </ul>	<p>Guiding Principle 3 states that the Data Exchange Framework will support whole person care, including health information exchange and use to:</p> <p>“Identify and manage population health; improve transitions of care; track and report quality; improve health equity; and coordinate care and services”</p> <p>Proactive data sharing by hospitals when patients are hospitalized is the most basic and essential way to improve transitions of care and support care coordination through information exchange.</p> <p>This must be accomplished by push, not query, because care teams need this information in real time and often do not know when their patients are hospitalized.</p> <p>Proactive data sharing is also needed to achieve the “real-time access” requirements of the AB 133 law:</p> <p>“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...”</p> <p>This is an area where the benefit of QHIOs is very clear. After hospitals share a complete data feed with at least one QHIO, the QHIO will match these data to the patient panels of providers, plans and other QHIOs, facilitating one-to-many exchange.</p>
5	Clarification of QHIO fees	Policy – Permitted,	Edit page 2 as follows:	Participating providers and plans will pay a portion of QHIOs

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		Required and Prohibited Purposes	<p>a. Participants are prohibited from charging fees to other Participants for any exchange of Health and Social Services Information under the DSA. <b>For clarity, this does not preclude entities from paying fees to the qualified health information organizations (QHIOs) they have selected to help them meet their own data sharing obligations.</b></p>	operating costs through subscription fees. The DSA should clarify that this is acceptable.
6	Definition of health care operations	Policy – Permitted, Required and Prohibited Purposes	<p>Edit page 2 as follows:</p> <p><b>“ ‘Health Care Operations’ shall have the same meaning 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. ”</b></p>	<p>The DSA should require exchange for all Operations purposes defined in HIPAA.</p> <p>Absent a clear and compelling reason for excluding certain permitted Operations activities, which has not been articulated, CalHHS should use the HIPAA definition of Operations to ensure alignment with HIPAA as required by AB 133:</p> <p>“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”</p>
7	Prohibited Purposes	Policy – Permitted, Required and Prohibited Purposes	<p>Strike this language:</p> <p>“Unless otherwise permitted by Applicable Law, Participants shall not, for their own indirect or direct financial benefit, re-use, re-disclose, aggregate, de-identify, re-identify or engage in the Sale of Health and Social Services Information received through the DSA without explicit written authority to do so from the appropriate party. A Participant shall not be considered to be acting for its own benefit if:</p> <p>(i) The Participant is a Business Associate and has a legally enforceable written agreement authorizing the re-use, re-disclosure,</p>	<p>We strongly recommend that CalHHS remove this section.</p> <p>The language is sweeping and will have many unintended consequences.</p> <p>The entire point of the Data Sharing Framework is to support the lawful use, aggregation and re-use of patient health information to improve patient care, enhance care coordination, and reduce costs.</p>

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			<p>aggregation, de-identification or re-identification of such Health and Social Services Information. This shall not include the Sale of Health and Social Services Information;</p> <p>(ii) The Participant is performing Individual Access Services at the direction of an Individual User or an Individual User’s Personal Representative; or</p> <p>(iii) The Participant is a Social Services Organization and has a legally enforceable written agreement authorizing the re-use, re disclosure, aggregation, de-identification or re-identification of such Health and Social Services Information with a government entity, Government Participant or other Social Services Organization. This shall not include the Sale of Health and Social Services Information.”</p>	<p>Yet these lawful purposes will be prohibited by this language.</p> <p>If the intent of this language is to ban the sale of identifiable patient data exchanged through the DSA, CalHHS could replace this language with new language extending the existing HIPAA restriction on the sale of PHI (identifiable data) to all Participants.</p>
8	Breach notification timeline	Policy – Breach Notification	<p>Edit page 1 as follows:</p> <p>Delete all text in section III (1) “Obligations of Participant”</p> <p>Replace with:</p> <p><b>Each Participant shall be expected to follow the timelines and processes for breach notification in whatever law and policies they are subject to.</b></p>	<p>The DSA should not impose new breach notification timelines and processes that diverge from existing state and federal requirements, including HIPAA.</p> <p>We recommend CalHHS incorporate state and federal law by reference and not create new breach notification timeframes via the DSA.</p> <p>For example, licensed health care facilities in California have up to 15 days (22 Health and Safety Code §§ 79902) to report a breach to the Department of Public Health, and Business Associates under HIPAA have 60 days to report a breach to Covered Entities (45 CFR §§ 164.400-414). The 72-hour and 10-day standards are burdensome and impracticable for organizations.</p> <p>In addition, we strongly recommend that reporting should be made as required by these state and federal laws, not</p>

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				using a new process nor to a new organization that will be unequipped to receive and investigate these breach notifications.
9	Medicaid Enterprise System (MES) funding	California Data Exchange Landscape	<p>The section on “Federal Initiatives to Advance Data Exchange” should include a discussion of the availability of Medicaid Enterprise Systems (MES) funding from CMS, which provides enhanced federal match for states to build and operate HIE services that advance their Medicaid priorities.</p> <p>The section on “California Initiatives to Advance Data Exchange” should note that California can still take advantage of MES funding to support HIE services that advance Medicaid priorities. As shown at the CMS link in the column to the right, many other states have successfully transitioned their HIE funding models from HITECH to MES.</p>	<p>References:</p> <p>"Designing a Statewide Health Data Network: What California Can Learn from Other States" (California Health Care Foundation, March 2021), <a href="https://www.chcf.org/wp-content/uploads/2021/02/DesigningStatewideHealthDataNetworkCalifornia.pdf">https://www.chcf.org/wp-content/uploads/2021/02/DesigningStatewideHealthDataNetworkCalifornia.pdf</a></p> <p><a href="https://cms.gov.github.io/CMCS-DSG-DSS-Certification-Staging/Outcomes%20and%20Metrics/Health%20Information%20Exchange%20(HIE)/">https://cms.gov.github.io/CMCS-DSG-DSS-Certification-Staging/Outcomes%20and%20Metrics/Health%20Information%20Exchange%20(HIE)/</a></p>
10	Hospital participation in HIOs	California Data Exchange Landscape	<p>Together with other HIOs, we calculated that as of 2020 about 50% of California’s non-Kaiser hospitals participated in one of our HIOs, far less than the document’s statement that 80% of California’s hospitals participate in HIOs. We also cannot find a copy of Dr. Adler-Milstein’s paper that you reference.</p> <p>Please delete the following references as they cannot be verified with public sources and contradict the informal count California’s HIOs completed:</p> <p>“The proportion of acute care hospitals participating in an HIO has also steadily increased from 25% in 2012 to almost 80% in 2019, exceeding the national average of 67%”</p> <p>“Additionally, the proportion of smaller hospitals that connect to an HIO (68%) is approximately 10 percentage points lower than the proportion of medium-size (81%) or large (79%) hospitals.”</p>	
11	Health plan need for clinical data	California Data Exchange Landscape	The “Health Plan” section should mention that although many health plans in California participate in HIOs, they still cannot access timely and complete clinical data for care coordination, quality improvement (e.g., HEDIS reporting and care gap closure), and	

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			<p>population health management (e.g., risk stratification) due to low provider participation.</p>	
12	Health plan participation	California Data Exchange Landscape	<p>Per above, in the “Health Plan” section please delete this figure as it cannot be verified with a public source:</p> <p>“Less than half (42%) of California’s HIOs report that private health plans contribute data, view or receive data, or pay to participate.”</p> <p>Also, the appropriate way to measure health plan participation would be the percent of California health plans that participate in a HIO, not the percent of HIOs reporting health plan participation.</p>	
13	HIO coverage	California Data Exchange Landscape	<p>Enterprise HIEs are not typically included in the “HIO” category so recommend you delete the reference to enterprise HIOs in the HIO section.</p> <p>Also please edit the HIO section as follows:</p> <p>“To summarize, as of August 2021, 15 <del>regional</del> HIOs in California <del>served participants in at least 39 of 58 counties and</del> exchanged more than 20 million patient encounter messages per month.<sup>80</sup> <b>Of these, 7 HIOs qualified for and actively participated in</b> Cal-HOP, <b>which</b> played a role in increasing provider participation in <del>regional</del> HIOs, with 390 qualifying provider organizations achieving the first milestone, basic connection to a qualifying HIO, and 341 (87.4%) achieving the final milestone, adoption of advanced data exchange interfaces.<sup>81</sup>”</p> <p>“However, gaps in <del>regional</del> HIOs’ reach and capabilities remain, <b>since many provider organizations still do not participate.</b> There are <del>still approximately 19 counties that are not served by any of California’s regional HIOs, and in the counties that are served, not all provider organizations participate.</del>”</p>	<p>Not every HIO is regional.</p> <p>Seven HIOs actively participated in Cal-HOP.</p> <p>Manifest MedEx serves every county in the state so the statement that there are 19 counties not served by a HIO is false.</p>
14	Governance	Data Exchange Framework Governance	<p>We strongly recommend that the following functions remain the direct responsibility of CalHHS and not be delegated to the Policy Board:</p>	<p>Functions like issuing regulations and conducting enforcement are inherently governmental and require</p>



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		Governance Model and Implementation Approach	<ul style="list-style-type: none"> <li>Drafting and finalizing regulations</li> <li>Establishing specific standards or requirements for data sharing</li> <li>Drafting and revising Policies</li> <li>Enforcement with respect to whether entities sign the DSA and comply with data sharing requirements</li> </ul>	<p>expertise, oversight, resources and authority that are housed in government. For this reason, they should not be delegated to the Policy Board.</p> <p>Instead, the Policy Board should be charged with high level policy direction including assessing whether the data sharing goals established in AB 133 are being met.</p>
15	Public funding of HIOs	Health Information Exchange in California: Gaps and Opportunities	<p>Please acknowledge the lack of funding for CA's HIOs in Gap 2 by adding this sentence at end:</p> <p><b>"In addition, unlike in many other states, California's HIOs are not publicly funded as core infrastructure, which constrains the scope of their services and their benefit."</b></p>	
16	Public funding of HIOs	Health Information Exchange in California: Gaps and Opportunities	<p>Please acknowledge the need for a HIO funding approach by editing Opportunity 2.2 as follows:</p> <p>Opportunity #2.2: Data Exchange Intermediary Qualification <b>and Funding</b> Process. The state should <del>establish policy that leverages national programs that</del> define a qualification <b>and ongoing public funding</b> approach for <b>Qualified Health Information Organizations (QHIOs)</b><del>data exchange intermediaries</del> and should further specify additional state data sharing requirements pursuant to AB133 that should be incorporated into the DxP Data Sharing Agreement (DSA) and Policies and Procedures (P&amp;Ps).</p>	<p>Use the term "Qualified Health Information Organization" to mirror the language in the DSA</p> <p>Funding for California's HIO infrastructure is an important opportunity that was repeatedly discussed by the Stakeholder Advisory Group.</p>
17	Use of MES	Health Information Exchange in California: Gaps and Opportunities	<p>Recommend adding a discussion of how HIE infrastructure can be funded through MES to the MES section.</p> <p>For background we have appended a memo summarizing other states' approaches to using MES funding to support HIE infrastructure.</p>	
18	Authority used for data sharing incentives	Health Information Exchange in California: Gaps and Opportunities	<p>Edit the CMS Medicaid matching fund section:</p> <p>"Arizona, for example, has leveraged federally matched dollars to establish a data sharing incentive program that</p>	

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			<p>increases payments for eligible entities that share data with Health Current, the state’s designated health information exchange.<sup>108</sup> <b>Arizona uses the directed payment authority in 42 CFR 438.6(c), the same authority used to make Proposition 56 and hospital Quality Incentive payments in California.”</b></p>	
19	Social service organizations	Overall revisions needed	Delete reference to social service organizations and issue a revised DSA and policies including them by January 2023.	<p>We are concerned that many of the policies and approaches outlined do not readily apply to non-HIPAA covered entities.</p> <p>Rushing to include them in the DSA and Policies may imperil the implementation and legitimacy of the whole Data Exchange Framework.</p> <p>An example of a concept that needs more consideration is the proposal that HIPAA privacy and security requirements apply to all these organizations, whether or not they are covered by HIPAA as covered entities or business associates. In our view a small social service organization will simply not be able to meet HIPAA requirements, and the underlying concept of TPO (which is the basis of the DSA’s permitted purposes) will not be understandable or apply to them.</p> <p>Also, unless they are a covered entity or business associates, providers will need to obtain consent before sharing data with social service organizations. There is not yet a scaled process, or standardized approach, for obtaining this consent. Until these things are in place, we expect that providers will refuse to respond to any request for clinical data from social service organizations, which will be complicated and disruptive and</p>

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				<p>undermine the purpose of the Data Exchange Framework.</p> <p>We agree completely that social service organizations should be included in the Data Exchange Framework. But we think more time, thought, and policy development are needed to do this in a smart and viable way.</p> <p>Since social service organizations are not required to sign the DSA by January 2023, we strongly urge CalHHS to take additional time to more fully and completely think through how these organizations will be treated.</p> <p>One option, in the near term, is to only permit social service organizations that are business associates of covered entities to sign the DSA. This means they have signed a business associate agreement (BAAs) that outlines their TPO role and binds them to HIPAA privacy and security requirements. We expect most organizations providing community supports under Cal-AIM will sign BAAs with health plans.</p>

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 25 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 Final Budget passed by the Governor 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