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May 15, 2023

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

Re: Comments on Draft Qualified Health Information Organization (QHIO) Application and Draft QHIO Program Policy and Procedure (P&P)

Dear John:

Thank you for the opportunity to comment on the draft QHIO application and accompanying P&P on the QHIO Program. The release of these documents marks a milestone on the road toward implementing the Data Exchange Framework (DxF). As early as this summer, QHIOs will be designated by CDII as having demonstrated their ability to meet DxF requirements and assist signatories complying with the Data Sharing Agreement (DSA), while protecting sensitive information for millions of Californians. The stakes for the proper selection, expectations, and oversight of QHIOs are paramount to the success of the DxF.

We urge CDII to adopt lessons and structures from other states and regional and national organizations that have successfully established digital health data infrastructure that serves the needs of their populations broadly, and Medicaid and public health programs specifically. In particular, CDII should approach the QHIO Program as a foundation to establish *health data utility (HDU)* infrastructure for California to advance digital equity—and thus health equity—across state and local programs, including CalAIM, social and community supports, and public health. This HDU concept has been articulated by a wide range of expert organizations: Civitas' HDU Framework, the Consortium for State and Regional Interoperability (CSRI's) HDU Maturity Model, and the American Legislative Exchange Council's model HDU state policy. We expand on some of the concepts and characteristics of HDUs below.

Felix Su, Manifest MedEx's Policy Director and Implementation Advisory Committee (IAC) member submitted our detailed feedback via the *DxF QHIO Comment Template* as requested by CDII. This letter summarizes the critical recommendations and rationale from our comments, which are grounded in the *QHIO Program Guiding Principles* developed by CDII in consultation with the IAC.

<u>Equity.</u> The program will create opportunities for many signatories to successfully participate in the DxF

<u>Recommendation: Require QHIOs to Serve All Signatory Types and Purposes</u>

One of the highest callings of the DxF is to close the digital divide that continues to exist for many independent and rural providers, as well as managed care plans serving the state's most vulnerable. We are therefore deeply concerned with draft application's revised question that merely asks QHIOs to disclose "any limitations or restrictions that limit the DxF participants who are eligible to contract for the QHIO's services." This completely upends the equity principle. Because no DSA signatory will be required to use a QHIO, and all are free to select any technology vendor or network that meets their needs, the state has little to lose by requiring this of QHIOs and much to gain. The DxF should strive to create an

environment where every signatory *is able to* use a QHIO to comply with the DxF even if they are unable to use other means. Digital equity demands an inclusive health data safety net with onramps for all signatories to connect. A fundamental starting point is for every QHIO to welcome and enable the participation of any health care provider, health plan, or public health organization in its service area. We urge CDII to restore this requirement.

Recommendation: Require QHIOs to Be Non-Profit

A foundational characteristic of an HDU is the ability to serve in a neutral capacity to meet a broad range of stakeholder data and connectivity needs and operate in the interest of the public. There is consensus across the existing and emerging HDU frameworks and models that to truly serve in this role, HDU infrastructure must be facilitated either by non-profit organizations or directly by state government agencies. These conditions are necessary for a health data safety net—inclusive and transparent governance with business motives that are not focused on financial returns for shareholders.

Indeed, through statute or regulation, AZ, DC, DE, NY, and WI expressly require non-profit status as a condition of HIO designation/certification. At least 13 other states have exclusively designated non-profit HIOs to provide statewide health information exchange infrastructure—reflecting the importance and gravity of carefully using state authority to designate only those organizations that can serve as neutral conveners and exchange facilitators in the interest of the public.

To that end, we recommend that CDII align the QHIO program requirements with this fundamental aspect of HDU infrastructure and require organizations designated as QHIOs to be incorporated as *501c3 non-profits* with a public mission that, at a minimum, matches CalHHS' vision to enable the exchange of health and social service information across our state's communities in a manner that improves and enhances the health and wellbeing of Californians.

Vendors and networks whose incentives are driven by financial demands of shareholders, venture capital or private equity do not invest in connections and capabilities for DSA signatories that are underserved and under-resourced because they are the least profitable—often not profitable for tech vendors—and thus have historically been left behind. This reflects the current state of health information connectivity and exchange in California today. The state has a unique opportunity to counterbalance this status quo through the QHIO program by ensuring QHIOs represent a set of non-profit organizations willing and able to support connectivity and data exchange even where it is not profitable to do so. The state should do this because it is the right thing to do. This is the true meaning of establishing utility infrastructure that enables a digital health data safety net.

A simple approach for CDII to do this is to align the concept of a QHIO with the HDU Maturity Model developed by CSRI. This maturity model demonstrates a stepwise evolution to HDU infrastructure that accounts for multiple organizations at a variety of maturity levels to support a health data safety net. The CSRI model would define a QHIO as "a *not-for-profit entity* responsible for basic connectivity and designated by the state to operate a…network *which everyone can access*, like an electric or water utility model." (emphasis added)

<u>Confidence.</u> The program shall provide signatories with confidence in the quality and level of service offered by HIOs that have been qualified by CDII

<u>Recommendation: Expedite Required ADT Capabilities and Limit QHIO-to-QHIO Roster and ADT Sharing to DSA Compliance</u>

Participants should be confident that QHIOs are ready from day one to support all transaction patterns required by the DSA and its P&Ps. Receiving, processing, and forwarding Admit, Discharge, Transfer (ADT) notifications to all requesting Participants is one of the most basic yet essential functions. We recommend the required implementation dates for QHIOs to have *all* ADT capabilities be moved up to January 31, 2024, to coincide with mandatory signatories' requirements to begin exchanging data.

Because QHIOs will share and monitor ADT events for each other's rosters, it is necessary for them to build and maintain trust as the intended ADT brokers for millions of patients among hundreds of hospitals and thousands of care teams. The final QHIO application and P&Ps should prohibit QHIOs from using data from shared rosters and associated ADT messages for purposes beyond delivering notifications to the appropriate QHIO and/or DSA signatories for HIPAA permitted purposes or as authorized by the subject of the ADT message, unless the QHIO has a separate business arrangement with the ADT data source/hospital for broader use of data from their ADT feed.

<u>Recommendation: Continue to Require HITRUST r2 Certification</u>

We strongly support the revisions in the draft application to (1) limit the sole recognized security certification to HITRUST r2 and (2) stipulate that "applicants will not be qualified until HITRUST r2 certification is achieved." The intensity of effort and resources involved to obtain this certification is commensurate to the volume, sensitivity, and regulatory complexity of data and personal information that QHIOs will store, manage, and transmit on behalf of Participants.

Some stakeholders have asked for HIOs to be provisionally qualified while still working to achieve their security certification. CDII should not invite what could represent substantial harm to individuals and Participants, and reputational damage to the DxF and QHIO Program, by signaling confidence for signatories to rely on designated intermediaries that have not yet cleared the bar of having industry-standard security and privacy controls. An uncertified QHIO suffering a major breach or other incident that could have been prevented by these controls would likely cascade into trust faltering across *all* QHIOs—including those that have implemented and maintained the proper security safeguards—and a severe erosion of stakeholder confidence in the state's framework for designating QHIOs.

<u>Stability.</u> The program aims to create stability so that QHIOs and signatories can make business decisions with minimal concern for change or disruption

<u>Recommendation: Raise Cash Reserve and Liability Insurance Requirements</u>

Every QHIO must demonstrate it is on sure financial footing as a going concern—especially since the QHIO will be part of a digital health data safety net meant to support all Participants at a statewide scale. This

means CDII should reset the cash reserves requirement from four to six months, which is the reasonable benchmark of financial stability proposed in the original draft of the application.

Similarly, the proposed coverage requirement for liability, errors and omissions, and cyber risk is inadequate given the volume of sensitive data and personal information that each QHIO will manage as a state-designated intermediary. We recommend requiring every QHIO to be insured for at least $5 million per incident and $10 million per annum for general liability and errors and omissions, and at least $10 million per incident/annum for cyber risks.

Recommendation: Implement Annual Attestation to Maintain QHIO Status Without Reapplying

CDII should stipulate that once qualified, QHIOs are not required to reapply in following years if they annually attest to and meet program criteria (accompanied with appropriate monitoring by CDII). Otherwise, Participants may perceive the program as being unstable due to lack of durability in qualified status and uncertainty of exits among intermediaries that may serve large numbers of signatories.

Fairness. The program design will be fair, offering all participants reasonable time to adapt to change and/or remediate issues

Recommendation: Develop New P&Ps Dedicated to QHIO Program, Including What Constitutes Compliance or Success

Fairness begins with all QHIOs having a clear understanding of their ongoing service and compliance responsibilities to Participants and CDII, and the processes for monitoring and enforcing those obligations. The standards by which QHIOs are evaluated and designated should be transparent for DSA Signatories as well. The initial application and P&P are insufficient for this. We strongly recommend that CDII develop a new set of QHIO P&Ps that set forth the actual requirements QHIOs must meet to receive and maintain their qualified status. These P&Ps should fully delineate the administrative processes of the QHIO Program (attestation and monitoring, complaints, appeals, etc.) and in articulating requirements should provide clarity about what constitutes compliance for any components included in the QHIO application. We also recommend that the QHIO P&Ps consolidate QHIO-specific technical requirements for exchange that are currently scattered and have repeatedly confused stakeholders participating in CDII DxF committees. This approach will provide clarity and transparency for all QHIO applicants and DSA Signatories regarding the standards and ongoing expectations for QHIOs.

Recommendation: Allow QHIOs to Remediate Issues

Despite CDII's stated fairness principle, neither the draft application nor P&P contain any mention of opportunities for QHIOs to *remediate* issues. Suspension and termination of qualified status are the only listed penalties. These are drastic actions that should be reserved for QHIO acts or omissions that create an immediate threat or will cause irreparable harm to Participants, individuals, or CDII. We recommend that CDII formally incorporate the six-month QHIO probationary status discussed at a previous IAC meeting, and other administrative actions that are proportionate to less severe issues with QHIO

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compliance or performance. Under these lesser sanctions, QHIOs should retain their qualified status and be allowed to appeal the action or remediate the issue.

Sincerely,

Erica Galvez
Chief Executive Officer

CC: DeAnne McCallin, Deputy Director, CDII
Cindy Bero, Senior Advisor, Manatt Health Strategies
Helen Pfister, Partner, Manatt Health Strategies
Jonah Frohlich, Senior Managing Director, Manatt Health Strategies