Manifest MEDEX

3993 Jurupa Avenue
Riverside, CA 92506
951.686.1326
www.manifestmedex.org

June 16, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services (CMS)
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Submitted electronically via Regulations.gov

RE: Request for Information (RFI): Health Technology Ecosystem [CMS-0042-NC]

Dear Administrator Oz and Assistant Secretary Keane:

Manifest MedEx (MX) appreciates the opportunity to provide feedback on the RFI: Health Technology Ecosystem [CMS-0042-NC], which poses a number of important questions for the future of nationwide health data exchange. MX is the largest statewide and not-for-profit health information exchange (HIE) in California. We combine a range of clinical, administrative, and social data to deliver longitudinal health records for 38 million unique individuals across thousands of network participants. MX's network comprises primary care and specialty practices, home health agencies, general acute care hospitals, accountable care organizations, laboratories, and 18 different payers, including eight Medicaid managed care organizations.

MX supports payers and accountable care organizations participating in value-based care arrangements through timely, insightful, and actionable data on both individual- and population-level health needs. This includes delivering ~1.6 million hospital admission, discharge, and transfer notifications per month and providing validated clinical data that can be used for reporting HEDIS® measures and closing care gaps. MX accomplish this by

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aggregating, matching, de-duplicating, and normalizing person-level data from many sources in our secure HITRUST CSF® certified environment.

MX participates in both the eHealth Exchange national network and their implementation of the Carequality framework. We are also a TEFCA participant via the eHealth Exchange QHIN. We were an early adopter of FHIR® APIs and continue to expand our FHIR-based exchange capabilities. We share the goal of empowering individuals with their own health information as they exercise self-agency, making data-informed and collaborative decisions about their own health and health-related goals. As such, we have established technology partnerships that streamline how individuals directly access all the data we have received on them from providers and payers using modern identity proofing and authentication methods, including CLEAR® I.D.

As the introduction suggests, our experience and perspectives span many of the recurrent themes and use cases presented in this RFI. To avoid duplication and condense our input, we have focused our responses to the specific question and its subsections below.

PC-11. How are health information exchanges (HIEs) currently helping to advance patient access to health information in the real world?

a. How valuable, available, and accurate do you find the data they share to be?

Value and availability: A patient or member portal contains only the health data originated and maintained by the provider, hospital, or health plan offering it. In contrast, high-performing HIEs securely aggregate, normalize, and match an individual's health data across networks of providers, hospitals, health plans, and other HIPAA covered entities to create longitudinal health summaries. These summaries include encounter information, lab results, radiology reports, medications, immunizations, and other key information consolidated into a single health record, giving individuals and their care teams as complete a picture as possible of the individual's health history. An increasing number of HIEs (including MX) provide this information to individuals for use in whatever health app or other technology platform the individual prefers to use. Allowing individuals to select the tools in which they import and use their own data makes health information far more useful than requiring them to log into and use a provider or payer portal.

Accuracy: High-performing HIEs do not simply ingest clinical and administrative health information from various data feeds but actively improve its quality and usability. They clean, parse, and organize data so there is a unified longitudinal record for each individual that can be exposed for a range of HIPAA-permitted purposes via APIs, and aggregated to

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understand population and public health. They also use sophisticated methods for comparing and matching health records to patient identities while protecting privacy.

b. What changes would you suggest?

High-performing HIEs that exemplify the *health data utility (HDU) model* (see response to next question) incur significant developmental and operational costs to:

- Build and maintain interfaces to hospital and ambulatory EHRs and health plan claims systems
- Clean, match, normalize and store clinical records, claims, encounters, and increasingly social information
- Maintain and continuously update attribution and eligibility files so that only plans and providers with an appropriate relationship to an individual can access their information
- Build and operate technical services including outbound data feeds to providers, health plans, and public health departments; event notification services; portals with longitudinal records; and systems to validate clinical data for quality improvement and reporting, such as HEDIS®
- Deploy and operate infrastructure needed for these services including enterprise master patient indexes, integration and data parsing engines, and data repositories
- Implement and maintain the highest security standards and protocols, which must evolve with ever-changing security threats
- Comply with state laws and regulation that evolve over time and often add more stringent requirements or limitations to data sharing than federal laws and regulations

Several states with robust HDU efforts receive 50-90 percent of their ongoing revenue from Medicaid and other public sources, in explicit recognition of the value they create for beneficiaries of these government programs. However, there has neither been a formal process for the federal government to recognize or certify state-designated HDUs, nor for states to request federal financial support for their established HDU infrastructure.

We recommend that CMS and ASTP/ONC jointly solicit proposals from states that seek to designate an HDU in support of greater effectiveness, efficiency, autonomy and responsibility in managing their own Medicaid priorities and public health functions. CMS

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and ASTP/ONC should require interested states to submit, as part of their HDU proposals, sustainable funding plans that may include requests for federal contributions through enhanced Medicaid match or public health grants.

c. Are there particular examples of high-performing HIE models that you believe should be propagated across markets?

We are a founding member of the Consortium for State and Regional Interoperability (CSRI), which firmly believes that each state should designate a statewide *health data utility (HDU)*: a single not-for-profit organization or small number of organizations with multi-stakeholder governance that provides secure exchange, curation, and analysis of health data to meet the comprehensive health data needs of both the public and private sectors within the state. HDUs represent the most effective, cost efficient, and well-governed approach to securely and appropriately meeting a wide range of stakeholder needs for health data at the local, state, and federal levels.

All HDUs begin with the core infrastructure and functions of an HIE, and many organizations that identify themselves as HIEs today are likely the best candidate in their given states to serve as a designated HDU. However, HDUs should also have a significantly broader profile of services than a typical HIE. CSRI has proposed and advanced a maturity model describing the characteristics and services of an HDU and the segments of health care and government it serves. While the model outlines a stepwise evolution toward HDU infrastructure that accounts for multiple organizations at a variety of maturity levels, we believe the following are crucial and nonnegotiable tenets for HDU designation:

- All HDUs should be capable of serving and welcome the participation of every health care provider, payer, and public health organization within their states, without bias toward these participants' geographical location, financial resources, or technical sophistication.
- HDUs should deliver value for a wide range of use cases, reflecting the unique needs and priorities set by their states and stakeholders. At the same time, there are foundational use cases that any organization deemed an HDU should support, tied to Medicaid and public health and requiring data aggregation at the state level:
    - Medicaid use cases should at a minimum encompass (1) program evaluation – enabling comprehensive analysis of the impact of 1115 waivers and other Medicaid services/programs, (2) comprehensive longitudinal health records—aggregating data from all relevant sources, including behavioral health and social programs, to produce unified health histories for Medicaid

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members that are made available through APIs, portals, and bulk data feeds; and (3) hospital event notifications—integrating hospital admission, discharge and transfer (ADT) data, matching ADTs to patient panels, rosters, and eligibility/attribution files, and pushing out notifications to primary care providers, managed care organizations, and other recipients to support transitional care management and evidence-based protocols that improve health outcomes.

- Public health use cases should start with electronic lab reporting, electronic immunization reporting, disease and syndromic surveillance, and electronic case reporting aggregated at the state level and shared as appropriate federally for timely, accurate, and data-driven decision-making.

Several states have robust, existing HIEs which have grown to deliver diverse services at significant levels of adoption, including the core Medicaid and public health functions delineated above. The throughline is these states' (1) recognition that trust across varied and sometimes competing stakeholders is critical to data sharing success and is best facilitated through transparent, multi-stakeholder governance; (2) foresight and understanding that multiple programs, services, and community needs require secure exchange, curation, and/or analysis of the same or overlapping health data; and (3) investment in corresponding aggregation of these functions into a single statewide not-for-profit HIE. These organizations serve as our best HDU models to date. We believe CMS and ASTP/ONC should highlight these models and promote the adoption or creation of an HDU in every state through federal program requirements, recognition of state designations and association certifications, and formal funding opportunities.

d. What is the ongoing role of HIEs amidst other entities facilitating data exchange and broader frameworks for data exchange (for example, vendor health information networks, TEFCA, private exchange networks, etc.)?

High-performing, not-for-profit HIEs fill critical service gaps left by national networks and frameworks like TEFCA and commercial vendor networks.

<u>Capabilities and Use Cases</u>

National networks and frameworks are EHR-centric in their design and deployment and have limitations that persist regardless of the trajectory of their participation or usage:

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- Providers participating in TEFCA and other national networks and frameworks typically only respond to treatment queries from other providers, and not to payment, operations, or public health queries.
- Payers cannot use national networks and frameworks to make administrative data—such as claims, encounters, and medication fills—available to provider organizations that need this information to succeed in value-based care arrangements.
- National networks and frameworks are based on participants initiating and responding to queries and individual patient record lookups. They do not support real-time data pushes such as event notifications of admissions or discharges. They do not provide the same proficiency in matching data across disparate data sources, and they do not provide the data aggregation, cleaning, or analysis that providers and payers need to make data useful for care coordination, population health, and quality improvement.

High-performing HIEs instead serve as both data pipelines and data refineries—collecting, combining, and cleaning clinical, administrative, and increasingly social data from thousands of sources. These HIEs set up data connections and manage data governance across their many participant-stakeholders, positioning them to:

- Turn data into information that is actionable and insightful for stakeholders
- Make both clinical and claims data available for care coordination, quality improvement and reporting, risk stratification and other uses cases tied to health care operations and payment
- Construct longitudinal health records that provide a complete and secure picture of an individual's health history
- Notify care teams about changes in a person's health status and transitions between institutional care settings

At the same time, high-performing HIEs cannot serve these roles and fill gaps created by national networks and frameworks without also being active participants in them. There is currently a shift in framework policies, including TEFCA, that moves to exclude HIEs from participating as equals to other entities. Should TEFCA continue in its current form, MX recommends revisiting TEFCA's Delegation of Authority policies to ensure HIEs/HDUs are more thoughtfully included.

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Trust and Governance

Most technology vendor health information networks are investor-owned and driven by the financial demands of shareholders, venture capital, and/or private equity. This dampens their incentives to provide data connections and capabilities for participants that are underserved and under-resourced, especially independent and rural providers.

Some for-profit companies cater toward functional gaps left by national networks and frameworks (e.g., event notification services) but retain historical data beyond the scope of these services (e.g., matching and forwarding notifications to requesting care teams). These companies often monetize the data they receive by reselling it to third parties, repurpose it for developing products, or otherwise reuse it without express authorization from individuals who are the subject of these data. Relatedly, there have been serious allegations against for-profit health data networks for violating nationwide frameworks' policies for both data use and reciprocity. These vendor practices risk eroding trust and hindering the participation necessary for network effects to take hold and enable a robust nationwide data exchange ecosystem.

The highest-performing HIEs and HDUs offer an alternative commitment to building and maintaining stakeholder inclusivity and trust, as both infrastructure and stewards of health information for millions of individuals among hundreds of health systems and thousands of care teams. To do so, they must credibly serve in a neutral capacity and meet a broad range of stakeholder data and connectivity needs, facilitated either by not-for-profit organizations or directly by state government agencies. Several states that have achieved or are on the path toward HDU maturity have required, through statute or regulation, transparent and not-for-profit governance along with secure and scalable technical infrastructure.

We look forward to further dialogue with CMS and ASTP/ONC to explore federal-state partnerships on the HDU model, either through CSRI or directly with our organization. Please don't hesitate to contact us for additional information or with questions about our comments.

Sincerely,

Erica Galvez
CEO, Manifest MedEx