



May 6, 2024

The Honorable Ami Bera
Member, House Task Force on Artificial Intelligence
ATTN: Request for Information—The State of Artificial Intelligence in Health Care
172 Cannon HOB
Washington, DC 20515

RE: Request for Information—The State of Artificial Intelligence in Health Care

Dear Representative Bera:

[Civitas Networks for Health](https://www.civitasforhealth.org) (Civitas) appreciates the opportunity to provide feedback on your recent Request for Information on the State of Artificial Intelligence in Health Care. Civitas is a national nonprofit collaborative comprised of more than 165 health information exchanges (HIEs), regional health improvement collaboratives (RHICs), Quality Improvement Organizations (QIOs), All-Payer Claims Databases (APCDs), and their business, technology, and professional service partners. Our members (including eight statewide and regional nonprofits in California) use data and multistakeholder, cross-sector approaches to improve health for individuals and communities, while educating and influencing both the private sector and policymakers on matters of interoperability, quality, coordination, and cost-effectiveness within the health system.

Civitas members have become leaders in the development of a new paradigm known as the Health Data Utility Model (HDU). The HDUs emerging around the country represent an evolution in the structure of health information networks and value-added capabilities, combining the multi-directional data transmission infrastructure of incumbent statewide and regional HIEs with a wider array of quality improvement, analytics, community health and social service functions of RHICs and related quality improvement organizations. The resulting HDUs take advantage of scaling efficiencies across well-defined geographies to better serve their communities as secure information networks and accountable, multi-stakeholder health data governance frameworks, as well as platforms for the integration of new technologies.

This role—as nonprofit, neutral, and public-interest platforms for the introduction of new technologies into state and regional health data ecosystems—is where emerging HDUs meet Artificial Intelligence (AI) at the leading edge of practical applications for machine learning (ML) and rapidly-advancing algorithmic innovation. Civitas members are by and large not developers of the type of generative AI that has (rightly) attracted significant attention from policymakers at the state and federal levels, and do not deploy in a diagnostic context what the Office of the National Coordinator for Health IT (ONC) labeled “predictive decision support intervention (DSI) technology” in its landmark HTI-1 rulemaking last year. Where our members are pioneering “use cases” for AI is in the enhancement of critical functions outside clinical settings that help manage data to improve the quality and efficiency of their operations, underwritten by shared governance approaches that become part of data-use agreements and standards.

As these use cases continue to evolve and expand (largely through nascent “ground up” collaboration between Civitas member organizations, vendors, healthcare providers, and industry

thought leaders), Civitas can make several general observations about the current and likely near-future “state of artificial intelligence” in our particular corner of the health care landscape, alongside recommendations for how we feel federal policymakers should approach them.

What are the various applications of AI in clinical or operational contexts?

Civitas members’ purview is the operational context, where the clinical data is collected, transmitted, filtered, analyzed, matched, and otherwise used with non-clinical data. Our members do not directly employ AI in the clinical context. Many Civitas members are infrastructure developers building comprehensive patient records in a state or region by connecting medical practitioners and other providers across health systems (which often use different proprietary electronic health record (EHR) platforms) in near real-time, and embedding them in networks of public and private payers for fiscal data; public health agencies for disease surveillance; government agencies for benefits and service determinations; and community-based organizations for other services that address the health-related social needs of the most vulnerable (and expensive) patients through care coordination. This listing does not include additional secondary contributors to these networks, such as researchers, value-based care arrangements (e.g. accountable care organizations) and clinical quality improvement initiatives working in to the public and private sectors on health transformation initiatives.

AI technology primarily serves to collate data in various ways that improve system accuracy and efficiency and patient experience. Of particular importance to the functioning of any emerging HDU is patient matching—ensuring that data entered from wide-ranging sources with diverse formats, data elements, and technical capabilities at different times is consistently attributed to the same record for the same individual. At the heart of this operation is the master patient index (MPI), against which all incoming information and all patient records are checked, and which must be constantly “cleaned” (updated to ensure that its data is current and non-duplicated). The consequences of inaccurate, fragmentary, or duplicated data are significant from the HDU’s operational perspective because they render its work product less valuable to participants and often require substantial investments in staff time and resources to correct. As errors ripple down the pipeline to clinical settings, bad data that misinforms medical practitioners and creates incomplete patient records can and does produce worse health outcomes for patients, including incorrect prescriptions and unnecessary tests that dramatically increase the cost of care.

This “data hygiene” at scale is essential, and the challenges are the same whether the organization is [San Diego Health Connect](#) in San Diego and Imperial Counties, [SacValley Medshare](#) in 21 northern CA counties, or [Manifest Medex](#) in all 58 CA counties. Large hospitals with multimillion-dollar EHR systems and urban county HHS departments attended by national IT contractors must connect to the network as seamlessly as rural doctors’ offices using fax machines; the data must be made equally readable and reliable, and the system must be able to handle ever-increasing transaction volume as new patients and services are added. The integrity of MPI data in turn affects the integrity of claims data that is run through statewide APCDs (such as California’s Health Care Payments Database), performance metrics developed and applied by QIOs, and more localized population health data that informs RHIC community projects.



Are there specific examples of AI applications that have significantly improved patient outcomes or streamlined health care processes?

In recent years, emerging HDUs have turned to AI for data cleaning and MPI enhancement that operates with varying degrees of customization. Most of the Civitas members who utilize ML capabilities have adopted them as “plug-in” applications offered by vendors of varying sizes in a competitive marketplace or integrated into other off-the-shelf software packages, similar to how IT solutions for cloud storage or cybersecurity are delivered. A few have embarked on more expansive and ambitious projects that see custom-built ML tools integrated into the architecture of their systems, working with developers to create tools like “smart” admissions-discharge-transfer (ADT) alerts attached to predictive analytic models that assess the likelihood of future medical scenarios based on the patient’s record.

Recent examples of these applications include data hygiene plugins that use multi-layered “identity resolution engines” to sort through mismatched pieces of information in a fraction of the time that would typically be required for manual work queues—and with better results, reducing the duplication rate in some HIE systems from as high as 30% to below 1%. Last year, San Diego Health Connect began using this type of software in partnership with the community health organization 211 San Diego, while SacValley Medshare signed a multi-year vendor arrangement in January for similar ML-infused operating system “modules” designed around autonomous analytics for claims and payer data streams. The vendors in both cases ([4Medica](#) and [Health Catalyst](#), respectively) are also among Civitas’ Strategic Business and Technology partners. More broadly, Civitas members believe that the following primary use cases at the patient and provider levels are bringing about critical improvement: personalizing treatment and patient engagement, improving response time to medical imaging analysis, population health and predictive analysis, and drug discovery both improve the patient experience and bring about important efficiencies in process. We also believe that the involvement of patients is critical to the success of these applications and of AI governance models. AI applications should be built with patients or communities of interest rather than for them.

What regulations, policies, frameworks, and standards should entities utilizing AI adhere to, and what mechanisms are in place or should be in place to supervise and enforce them?

Civitas and our members believe in multi-stakeholder, community driven governance of health data as a core part of our mission, and health data managed with AI capabilities is no different. As technology continues its rapid advance and health digitization increasingly moves from the “basics” of point-to-point medical information delivery to complex clinical and non-clinical integration, our experience is that ethics, privacy, equity, and the community trust that they ultimately make (or break) becomes even more essential. We support industry frameworks that can systematically embed these principles in our members’ service areas and standard operating procedures in accordance with applicable laws and regulations, building from legal baselines to create comprehensive platforms for broad-based stakeholder buy-in.

The nascent legal-regulatory architecture on AI in healthcare (such as the Biden Administration’s Executive Order 14110 on “Safe, Secure, and Trustworthy Development and Use of Artificial

Intelligence”) has largely focused on providers, payers, and developers in the *Health Insurance Portability and Accountability Act* (HIPAA) (“covered entities”), ONC certification, federal fee-for-service and managed care reimbursement contexts. Civitas members fall into none of these categories directly, but the federal rulemaking and best practice dissemination activities that the Administration has pursued to date are nevertheless important to our members’ operations and the long-term viability of their networks. Without practical quality control measures at points of data entry backed by force of law, the entire health data transmission and analytics pipeline risks being corrupted by (for example) race and sex discrimination as addressed by HHS-OCR’s recent modifications to Section 1557 of the Affordable Care Act, or confabulation as referenced in new NIST risk management frameworks for generative AI tools. The role of multi-stakeholder governance structures—such as those coalescing around emerging HDUs and their partners in statewide and regional service areas—is to augment and deepen the work of public authorities by bringing industry actors together around shared principles and objectives in neutral and inclusive fora.

Among Civitas members, state-designated HIEs and emerging HDUs that are currently present in 44 states have become a focal point for governance efforts. The typical state-designated HIE is overseen by a governing board comprised of senior state Medicaid and state department of health officials; representatives of state hospital, commercial payer, and medical associations; executives of large health systems, local PHA representatives, patient advocacy groups, community-based organizations, academic health centers, technology vendors, and other influential actors in its statewide service area. Many HIEs/emerging HDUs also draw on longstanding partnerships with state-designated APCDs (in the 20 states that have them, including California), RHICs, and QIOs, in addition to the arrangements that they have formalized with entities connected to the exchange that range from several hundred to thousands of organizations.

These arrangements have created natural “communities of practice” for health data exchange that incorporate HIPAA-compliant data use agreements (DUAs) and other legal certifications as well as feedback mechanisms and working groups focused on specific problems related to consent management, technical standardization, and improving access to marginalized communities. As different actors grapple with the novel challenges posed by AI, existing HDU communities of practice will become the natural venues for developing—and standardizing—collective approaches to the treatment of various data sets (identifiable and de-identified PHI, non-PHI SDOH data, consumer data, proprietary information, etc.) and specific use cases (diagnostic and lab data, state and local disease surveillance, claims analytics, etc.). Shared ethics guidelines and policies on transparency, discrimination mitigation, cybersecurity protocols, and contracting requirements will likewise be products of HDU convening.

The phased rollout of the California Data Exchange Framework (DxF) that began with the passage of AB 133 in 2021 and will continue for clinical and social service providers through 2026 illustrates HDUs’ potential to exercise this kind of leadership across the health ecosystem. Of the nine “Qualified health Information Organizations” (QHIOs) designated by the California Health and Human Services Agency to serve as official entry points, facilitators, and technical assistance providers for the DxF, five are Civitas member HIEs and emerging HDUs (Manifest Medex, SacValley Medshare, San Diego Health Connect, [Los Angeles Network for Enhanced Services](#),

and [Serving Communities HIO](#)). These organizations were selected not only because they already manage large segments of the state's inter-EHR connectivity as public benefit infrastructure, but because their resulting experience and deep engagement within their service area communities makes them ideal launchpads for new health data system components—whether those components are procedural like DxF or technological like AI. Each QHIO has developed sets of state-aligned DxF implementation protocols for its existing and future participants that have been incorporated into its DUAs, and is currently in the process of disseminating DxF best practices through virtual resource centers and hands-on training where needed (with a particular emphasis on social care agencies and CBOs). QHIOs will also work closely with CalHHS to monitor the progress of DxF protocol dissemination and conduct performance evaluations.

Are there legislative measures that Congress can take to ensure access to safe, reliable AI healthcare services?

Civitas supports the mission of the House and Senate Bipartisan Task Forces on AI to “explore how Congress can ensure America continues to lead the world in AI innovation while considering guardrails that may be appropriate to safeguard the nation against current and emerging threats.” The guardrails in question have been proposed in piecemeal fashion to date and include bills that would define standards for responsible AI use by federal agencies, require public notification when those agencies use generative AI in decision-making, and mandate regular algorithm risk assessments by health care systems, insurance companies, and CMS to mitigate bias in treatment and coverage determinations. While Civitas members are not clinical providers or payers and therefore less directly affected by most of these bills, algorithmic bias at the point of care threatens to compromise the integrity of the whole rest of the health data pipeline—making Congress' focus on mechanisms to screen it out very much warranted.

Privacy at all levels of the health data system is also a paramount concern for Civitas members. However, any federal legislation on health AI applications should take care not to impose “AI-specific” consent requirements beyond those which already apply (or would apply under future legislation) to all HIPAA covered entities and business associates—i.e., the Privacy Rule's operational consent and right to request requirements, as well as its broad allowance for the sharing of PHI by covered entities and business associates with PHAs (via explicit associate agreements) for public health purposes. HDUs and other Civitas members work extensively with state and local PHAs on a regular basis to enable data exchange that improves response and resource allocation (and increasingly, for value-based assessment, training, and care coordination) as a core part of fulfilling their public-service mandates, which makes the current PHA framework invaluable.

Civitas does not feel that the use of AI for data management purposes raises privacy concerns that are new or substantially different, on balance, from those raised by current or previous generations of software, especially given that AI applications in their mature forms provide demonstrably better privacy protections and information security. The same machine learning that can spot small statistical movements in vast reams of data and harmonize data sharing formats can also continuously monitor data usage patterns by covered entities and business associates, raise alerts, and maintain de-identified structures that make authorized attribution much more



difficult. Given this reality, a new AI-specific consent framework would add more layers of costly and time-consuming administrative bloat for no clear advantage.

At the intersection of AI and HDUs, Congress can help accelerate AI functionality across state and regional networks that Civitas members lead by supporting efforts to make better use of existing infrastructure (which was largely funded by federal investment). The second Fiscal Year 2024 appropriations package that passed in March (P.L. 118-47) enacted report language attached to the Senate’s LHHS bill (S.R. 118-84) which recognizes state-designated HDUs in congressionally-approved text for the first time, defining the model and directing HHS (via ONC and the Centers for Disease Control and Prevention (CDC)) to issue best-practice “policy guidelines” and “leverage existing authorities, funds, and other resources to construct policy and regulations that strengthen existing HIE infrastructure to facilitate their transition into HDUs.” Civitas is in the process of collaborating with both agencies to develop the structure and content of official materials that will fulfill Congress’ intent by endorsing HDUs as a practical option for ground-up state and local health data governance—including for AI capabilities and use cases. As this work continues, Civitas will be consulting with several of our congressional champions on the potential need for letters to ONC and CDC emphasizing the importance of following through on S.R. 118-84, and we would welcome the chance to discuss related steps with Members and staff of the Bipartisan House Task Force on AI.

Thank you again for the opportunity to comment. Please do not hesitate to reach out to Civitas if we can be a resource as we work together to understand the current and future state of AI and we employ critical oversight through community-governed structures. Such structures draw on decades of experience in building interoperable health data systems with guardrails to ensure privacy and security which are used to improve health and healthcare outcomes.

Sincerely,

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