

Open City Labs' Response to  
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# Executive Summary

The National Directory of Healthcare Providers & Services (NDH) represents the foundation for what could become a comprehensive Data Exchange Operating System for healthcare interoperability (DEOS) that could fundamentally transform how Americans access care and services across all sectors, while delivering significant savings in healthcare costs in Medicaid, Medicare, Veterans Administration, and private sector insurance, as well as reduced IT costs across HHS' 100 programs. Whereas, the National Directory represents a foundational infrastructure for reducing provider burden and maintaining more accurate directory data at lower costs. The DEOS represents a natural evolution that enables innovation, competition, and seamless care coordination while maintaining organizational autonomy and market-driven solutions, and laying the foundation for the security and data exchange needs of an agentic AI future. It also represents a foundational strategy for Secretary Kennedy's goal of addressing the healthcare cost crisis driven by chronic health conditions.

The social determinants/drivers of health, which includes access/affordability of healthy food, adverse childhood experiences/trauma, toxic stress, education/health literacy predict 70% of health outcomes and exacerbate chronic health conditions like diabetes, obesity and hypertension. Patients with two or more chronic health conditions account for 93% of healthcare spending, and 2/3 of all healthcare costs.

This Data Exchange Operating System would address four critical transformation areas that span HHS's more than 100 programs and thousands of implementing organizations:

## Whole Person, Care Coordination and Care Plans with API-Driven Eligibility and Enrollment Infrastructure

CMS has recognized the importance of addressing the social determinants of health by supporting both 26 states implementing 1115 Medicaid Waivers that have at least one social service paid for on a fee-for-service basis, as well as new Medicare codes for providing Medicare enrollees with navigation to evidence based social services when the social need is exacerbating patient chronic health conditions. Billing with these Community Health Integration and Personal Illness Navigation codes requires documenting interventions as part of a Care Plan. The NDH/DEOS would provide a mechanism for healthcare and social care providers to meet these care plan data exchange requirements, while streamlining enrollment in services. Currently social care providers sometimes have to enter data about clients into 18 separate systems/ Moving beyond form-based government services to programmatic access that enables real-time eligibility screening, automated enrollment, and personalized service recommendations, grant and regulatory reporting. Programs like SNAP reduce annual healthcare costs by \$1,400-\$4,100 and yet 58% of eligible older adults don't access SNAP benefits. Half of eligible families miss WIC enrollment, although it reduces the likelihood of preterm births by 48%. The problem isn't program design—it's infrastructure failure.

## AI Trust Registry and Security Framework

The NDH is envisioned to provide a single source of truth for providers attesting to information about their organization, services, and the electronic means (i.e. endpoints) to reach them in their EHR. This vision of being able to attest to that information once, and for thousands of other downstream directories to receive automatic updates will improve data quality, reduce costs and ensure more reliable data exchange across systems for a wide variety of use cases. Whereas the rise of AI's within any system have clearly defined security and data governance rules associated with them, the emergence of increasingly capable AI agents, which are/will be able to exchange data and complete tasks across a wide variety of systems, presents the need for new data governance and security frameworks. As healthcare increasingly relies on AI agents for care coordination, population health analytics, and clinical decision support, the National Directory could serve as the verification backbone ensuring these systems operate safely, transparently, and within appropriate privacy boundaries. An AI Trust Registry could enable autonomy and innovation while verifying alignment with established behavioral monitoring standards as part of a collaborative governance model without stifling competition.

## Privacy Preserving Measurement Platform

Outcomes measurement, whether that be population health analysis, FDA approved drugs, or measurement of health IT systems, or provider care quality, or AI performance require costly setup to ensure privacy and security, and typically require centralizing data, which creates lucrative targets for hackers. Privacy-preserving population health analytics would enable real-world evidence generation and support AI agentic deployment and continuous monitoring, and health IT impact assessment. The DEOS could support federated analytics architecture where organizations contribute to aggregate insights without exposing individual patient data, enabling breakthrough research in precision medicine. This federal, privacy preserving approach would show particular promise in advancing translational, epigenetic research, which looks at how health outcomes are shaped not just by genes, but by genetic expression, shaped by a person's environment, everything from food to exercise and trauma.

## (c) Regulatory Compliance as Commodity Infrastructure

Irrespective of what priorities emerge (e.g. value based care, quality measure/public health reporting etc.) a NDH can be envisioned as a tool for translating any set of regulatory rules and data exchange requirements into code, driving down the costs of regulatory compliance. Rather than requiring organizations to rebuild technology systems with each regulatory change, the National Directory could make compliance costs predictable and scalable. As AI capabilities advance, the marginal cost of adapting to new regulations approaches zero when built on standardized infrastructure, enabling rapid policy iteration without imposing massive technology burdens on providers.

By acting as common infrastructure across all HHS programs, this Data Exchange Operating System could generate dramatic savings in Medicare and Medicaid while reducing HHS technology budgets through elimination of redundant systems. More importantly, it positions the United States to lead global healthcare innovation by creating the conditions for a vibrant marketplace of interoperable solutions built on trusted, standardized infrastructure.

## Background: Two Independent Contexts for National Directory Use Cases

As the Founder & CEO of Open City Labs, my vision for transforming healthcare data exchange emerged from direct experience with the costly fragmentation that characterizes our current system. Working at Manhattan Psychiatric Center, Kirby Forensic Psychiatric Center, and Volunteers of America-Greater New York (VOA-GNY)—an anti-poverty organization serving as the largest residential services provider for veterans—I witnessed striking opportunities to improve care outcomes, while reducing cost. While patients in emergency rooms could seamlessly enroll in Medicaid using existing EHR data, clients seeking assistance with SNAP or WIC benefits had to navigate a maze of disconnected websites, each requiring manual data re-entry. Our staff

This pattern extended across all sectors. Healthcare providers, social service organizations, Head Start programs, and WIC clinics each maintained separate technology systems for essentially the same function: determining who is eligible for what services, when, and under what circumstances. The fundamental challenge wasn't program complexity—it was the absence of standardized data exchange infrastructure that could make eligibility determination and enrollment as seamless as any modern digital experience.

In 2016, I wrote about "government as a programmable platform," exploring what could happen if all government services—eligibility rules, enrollment processes, and regulatory compliance—operated through standardized APIs. The analogy was powerful: government technology procurement resembled the smartphone market before Apple's App Store. Nine years after the App Store launched in July 2008 with 800 apps, it hosted 2.2 million apps while iPhone users grew from 10 million to 814 million—an 81x increase. The platform enabled unprecedented innovation because developers could build solutions without rebuilding basic infrastructure.

The stakes for healthcare transformation are enormous. Supplemental Nutrition Assistance Program enrollment has been shown to reduce healthcare costs by \$1,400-\$4,100 per person annually, yet only 42% of eligible older adults access these benefits. Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) reduces preterm birth likelihood by 48%, saving \$58,917 per birth in healthcare costs, yet only 50% of eligible families enroll. These aren't program failures—they're infrastructure failures that cost lives and billions in preventable healthcare spending.

I founded Open City Labs in 2017 after presenting at TED's finalist selection process. Though my talk wasn't selected, TED staff encouraged me to "build it," and a friend running Medicaid Health Home programs told me, "everyone who runs my program nationwide needs your software." We hadn't written a single line of code, but the vision was clear: create the infrastructure that makes person-centered government services possible. Seven years later Open City Labs' CEO Matt Bishop worked with Bronx RHIO as a coauthor of the "Social Determinants of Health NYS Functional and Technical Specifications Document," in preparation for the 1115 Medicaid Waiver implementation, which facilitate SDOH data exchange across 6 health information exchanges. This comes after playing leadership roles in numerous national standards organizations, including 360x SDOH closed loop referral, and Gravity Project, SDOH Clinical Care, National Directory of Healthcare Providers and Services, and DirectTrust's Directory Policy, Directory Tiger Team and Consumer Credentials workgroups. Matt is a member of the HIMSS Social Determinants of Health Committee, HIMSS 2025 Health Equity Planning Committee and has spoken at the US Health & Human Services Office of Inspector General, HIMSS, Patient Center Medical Home Congress, United Nations, SXSW Interactive, Health 2.0, NYU & Columbia University.

Open City Labs has won awards from (federal government agencies) Administration for Community Living's Social Care Referral Challenge, (ANSI Accredited Standards bodies) DirectTrust "Interop Hero," and national foundation leaders, Robert Wood Johnson Foundation and AARP Foundation. As a coauthor of the "Social Determinants of Health NYS Functional and Technical Specifications Document," Matt has assisted states like New York with planning SDOH interoperability to meet 1115 Waiver requirements and address health equity. Matt is a member of the HIMSS Social Determinants of Health Committee, HIMSS 2025 Health Equity Planning Committee and has spoken at the US Health & Human Services Office of Inspector General, HIMSS, PCMH Congress, United Nations, SXSW Interactive, Health 2.0, NYU & Columbia University. He has leadership roles in numerous national standards organizations, including 360x SDOH closed loop referral, and Gravity Project, SDOH Clinical Care, National Directory of Healthcare Providers and Services, and DirectTrust's Directory Policy, Directory Tiger Team and Consumer Credentials workgroups.

## Original Vision for National Directory

Independently of Open City Labs' conception, the National Directory of Healthcare Providers & Services was originally conceived as a burden reduction project for reducing the cost of maintaining and updating directories. CMS has funded the HL7 FAST Patient Administration FAST National Healthcare Directory for Providers and Services data standard to develop an implementation guide. The standard envisions the NDH would serve as a single source of truth for information about healthcare and social care organizations, services, relationships and details for data exchange (i.e. electronic endpoints). Organizations/providers could enter their information once, and verify it periodically according to data quality rules in the national directory. Other downstream directories/systems would receive updates automatically to the updates to which it had "subscribed."



The National Directory could support better directory data quality and enable organizations to leverage Electronic endpoints that facilitate data exchange for a variety of use cases, including:

- Care transitions and referral coordination
- Health insurance enrollment processes
- Healthcare provider identification
- Healthcare service identification
- Provider verification and credentialing

Currently, numerous health and social service entities operate their own directories, encompassing providers, insurers, health information exchanges (HIEs/HIOs), health information service providers (HISPs), social service agencies, governmental bodies, and credentialing authorities. Yet these critical directory functions remain fragmented, poorly coordinated, and lack interoperability standards. Consequently, the healthcare ecosystem expends considerable resources and effort repeatedly collecting and verifying demographic data for both individual practitioners and organizational providers across multiple functions including data exchange, care coordination, professional licensing, credentialing processes, certification requirements, and reimbursement activities.

For example, in the US healthcare system, providers often have to contract with and regularly submit and update their information with ten or more plans. Maintaining these provider directories costs the US Healthcare system at least \$2 billion annually. In addition to the costs of maintaining directories, directory data is often low quality. A 2021 CMS study found that “52 percent of provider directory locations listed had at least one inaccuracy.”

Primary Sources would be designated as authoritative sources for contributing data or verifying the accuracy of data already contributed.

Potential primary sources include:

**National Plan & Provider Enumeration System (NPPES)** – HIPAA-covered entities use this to request and update National Provider Identification (NPI) numbers—10-digit identifiers for HIPAA transactions like claims, eligibility, and authorizations. Defines Type 1 (individual) and Type 2 (organization) providers.

**CMS Identity and Access System (I&A)** – Identifies individuals who can act on behalf of providers, managing staff and connections to CMS systems including PECOS and Medicare programs. Requires NPI before enrollment.

**Provider Enrollment, Chain, and Ownership System (PECOS)** – Enables Medicare enrollment, provider information updates, revalidation, and benefit assignment to third parties.

**Provider Transaction Access Number (PTAN)** – Confidential code assigned by Medicare Administrative Contractors for IVR authentication alongside NPI and TIN. Unlike public NPI/TIN

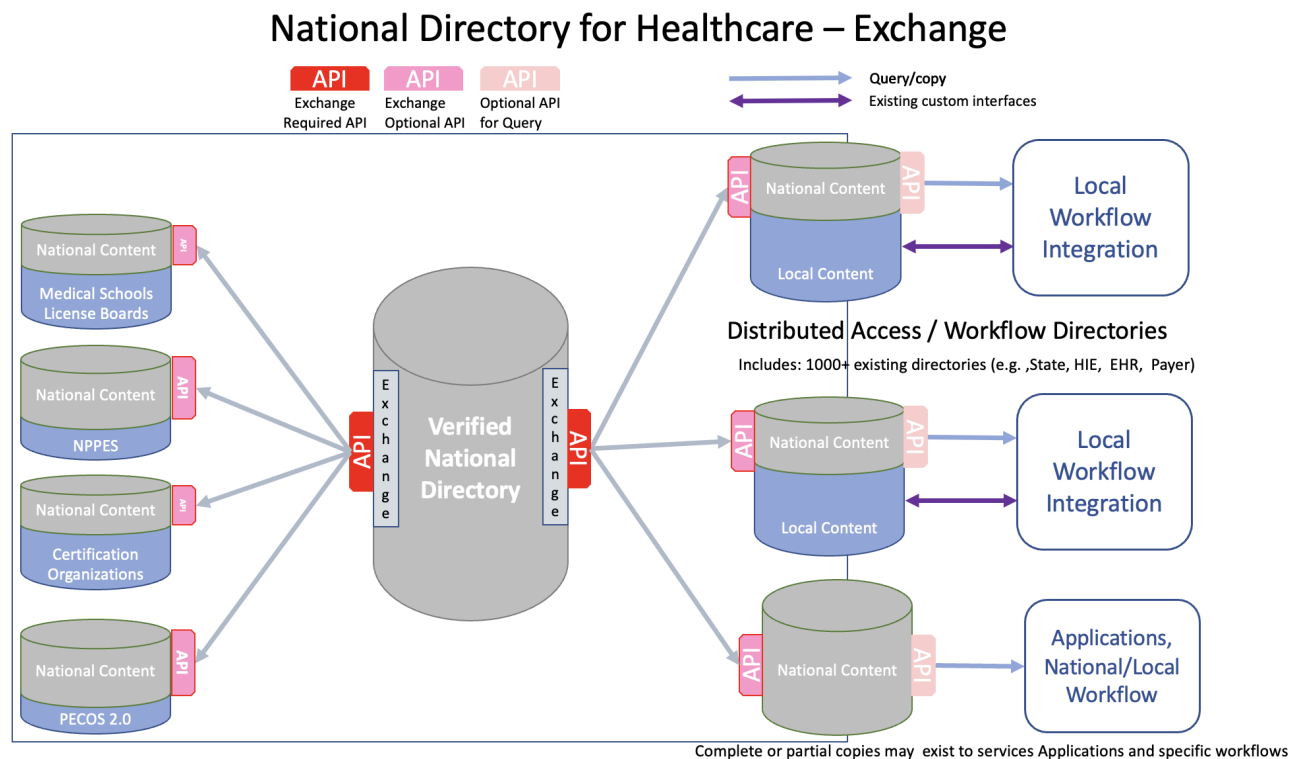
numbers, PTANs remain confidential with one-to-one NPI relationship per MAC jurisdiction.

**HCQIS Access Roles and Profile System (HARP)** – Secure identity management system for CMS quality measure reporting, similar to I&A.

**Quality Payment Program (QPP)** – Platform for providers and ACOs to report Merit-Based Incentive Program (MIPS) or Advanced Alternative Payment Models measures, evolved from EHR Incentive Programs.

**Medicare Physician Compare** – Provides beneficiaries with provider information including credentials, specialties, affiliations, and quality measures using data from PECOS, NPPES, MIPS, and claims.

**National Practitioner Data Bank** – Contains practitioner adverse events including malpractice settlements, licensure issues, clinical privileges, and DEA reports on healthcare practitioners.



The standard defines unique requirements for exchanging directories between the NDH and distributed workflow directories including a) Healthcare Directories, b) Social Service Directories and, c) Combined Healthcare and Social Service Directories.

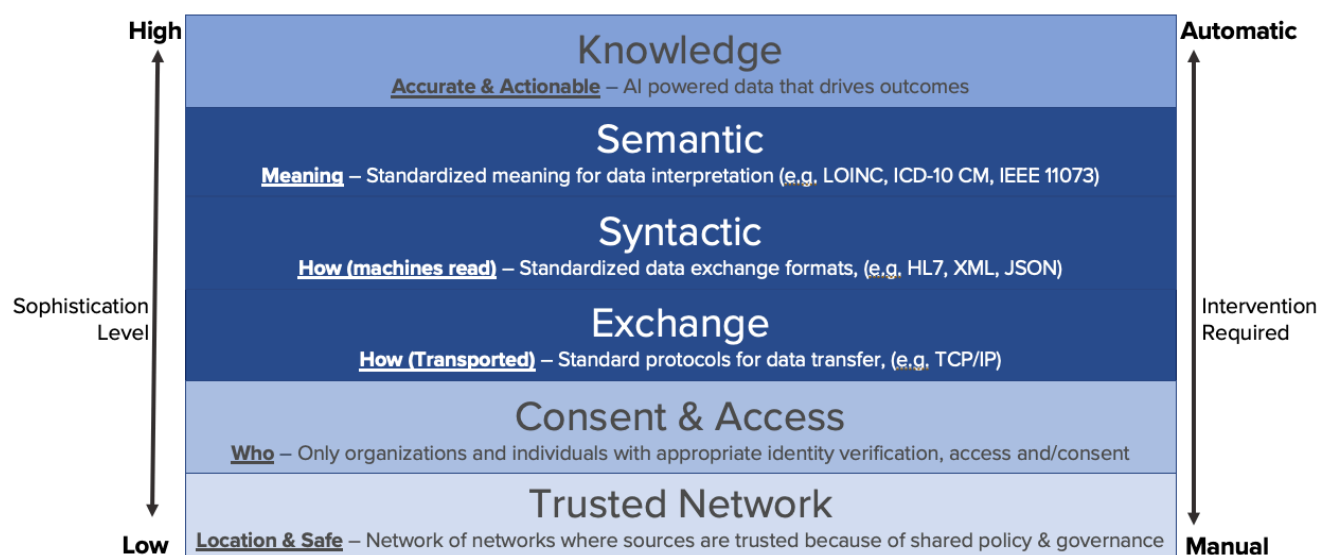
# How a National Directory Would Reduce the Cost of Data Exchange and Drive Innovation

Primarily, a National Directory would reduce the cost and reduce the time it took to integrate across systems, by providing software engineers with a greater portion of the information they need, and building on existing infrastructure. When other organization's endpoints are easily discoverable, fewer meetings are needed across departments, or with the engineering or product team of the data exchange partner.

As the diagram shows below, alignment in increasingly sophisticated elements of interoperability, leads to greater automation and less manual interventions. The ONC/ASTP and CMS have come a long way in funding the development of open standards like FHIR and in essential data requirements and definitions like USCDI, as well as standards for quality measures, value based care, and other healthcare domains (see dark blue in the center). We fully support these initiatives, which have focused primarily on data exchanged under the Treatment, Payment and Operations purposes of use under HIPAA.

While it may seem tempting to force consolidation of trust frameworks/trusted networks, picking winners and losers could stifle competition, and drive up healthcare IT costs, which would be particularly difficult for smaller organizations. Thus, a National Directory, or a network of networks would foster a thriving ecosystem of data exchange. A wider variety of data governance models would support the diversity of use cases, and give participants trust that their systems can seamlessly and securely access their patient's data via the variety of trusted networks/trust frameworks (e.g. TEFCA, Carequality etc.).

## Levels of Healthcare Interoperability



Matthew Bishop edited Oemic F. and R. Snelick in "Healthcare interoperability standards compliance handbook," pg. 13

These networks each have their own governance, legal obligations, standards, policies and certification requirements. A National Directory would maintain all the endpoints on the providers, across all networks, so that patient records could be located, accessed and unified. While patient consent, identity verification that would authorize access and authentication and security protocols for systems are out of scope for the National Directory, endpoint definitions can have a pointer to these further data governance requirements.

## Flexible Across Data Standards and Data Governance

While FHIR Endpoint is one Fast Healthcare Interoperability Resource (FHIR) amongst many, it can provide the foundational basis by which any data would be securely submitted and interoperable across a wide range of data standards (e.g. FHIR-REST, Direct, HL7v2 etc.) and implementation guides. This is important because irrespective of whatever funding decisions ONC/ASTP, CMS and HHS make, a National Directory can act as that universal lookup for where data is meant to be found.

To clarify, a National Directory would **not** include patient records. Nor would it need to maintain the level of complexity of each of the systems it describes. As an analogy, imagine you are guiding your grandma who is visiting your Mom who is in the hospital being treated for breast cancer. You get out Google Maps to get directions to the hospital (e.g. organization/provider). The nurse at the front desk directs you to the location of the Oncology Department (e.g. Service & Location) after you provide your Mother's name. As you get to the Oncology Department you inform the staff that your Mom only speaks Spanish (e.g. Endpoint). In other words, when engineers are trying to make systems exchange data, they need to know where they can send their public health data, or patient request data. By making these endpoints "advertise" what type of requests they understand, and data they can send, under what legal purposes. A National Directory could provide a framework for any regulatory transition from Certified Electronic Health Records to Certified APIs.

## Whole Person, Care Coordination and Care Plans and API-Driven Eligibility and Enrollment Infrastructure

The impact of social risk factors on health has become so compelling that 25 states have received approval and funding from the Centers for Medicare and Medicaid Services (CMS) to use Medicaid dollars to reimburse community-based organizations for providing certain social services, or navigation to services. CMS has also approved Medicare providers with reimbursement for assessing social needs and navigating patients with chronic health conditions to services that can prevent those chronic health conditions from being exacerbated. Approved service domains include: food, housing, transportation, intimate partner violence, and activities of daily living. They have explicitly called out navigation to government benefits like SNAP and WIC as legitimate services to be reimbursed on a fee-for-service basis. Amongst the

Medicare billing requirements for assessing and addressing social needs are to document interventions as part of a Care plan/Plan of Care.

The challenges that community-based organizations face are:

- Getting an adequate number of referrals when clinicians don't want to use separate systems to make social care referrals.
- How to meet new CMS requirements to document how social services are tied to chronic health conditions as part of care plans.
- Getting social care providers the data that they need, while being able to exchange data across a variety of clinical, social care, government, and payer partners.
- Duplicate data entry into up to 18 systems and not enough staffing to meet client needs.

While Medicaid Waivers and Managed Care Organizations provide some funding for SDOH investments, it remains a fraction of the largest social service programs like SNAP. Consider national Payor investments across all SDOH domain interventions (\$1.9 billion between 2017 and 2021). During the same time period \$378 billion was spent on SNAP alone, nearly 200X the amount spent by the largest 20 Managed Care Organizations covering the lives of 2 out of 3 Americans.

## Community Based Organizations Have Successfully Provided Important Benefits Enrollment Navigation Services

State and federal agencies have historically increased enrollment in government programs like SNAP, WIC or Medicaid by funding community-based organizations (CBOs) that have trusted relationships in hard-to-reach communities. While this has led to successful enrollment in for example [the Affordable Care Act Health Insurance Marketplace](#), too often the technology tools CBOs are equipped with by government agencies for this purpose are siloed enrollment systems that require duplicate data entry and do not integrate with the CBOs case management system. One Area Agency on Aging with a \$90 million budget must enter client data into eighteen distinct systems.

## Streamline Data Access & Enrollment via Application Programming Interfaces (APIs)

Application Programming Interfaces enable data to flow from one system to another, or functionality (like eligibility screening to be accessed across websites/apps). They enable data reuse, which makes possible auto filling forms for applying or recertifying for government programs. Despite bureaucratic misunderstandings, sharing data between state government agencies and with healthcare provider, payer, and social care provider partners for the purposes of informing people of their eligibility and streamlining eligibility enrollment is both legal and

commonplace. A National Landscape Analysis that surveyed 47 state government agencies on data coordination between programs showed that [90 percent of the states reported Medicaid and SNAP share data with at least one other program](#). Twenty-nine of the respondents who shared data had a full integration, meaning they had a single system for eligibility determination and staff played roles determining eligibility for two or more programs. Eight had partial integration and ten had no integration. Sixty six percent of respondents shared data with MCOs and 45% with non-profits. Despite this, non-API based methods used for data sharing varied and were not necessarily reproducible or scalable. None of the states shared SNAP enrollment data with third party organizations helping people enroll in benefits via APIs the way Medicaid enrollment and billing is made possible via APIs embedded in electronic health records. Building systems/apps for program enrollment that are meant to be interoperable with both healthcare and social care systems is essential to improving access to services because (1) of the vital role clinical and social care providers play in reciprocal service navigation; and (2) enabling consented data reuse to automate eligibility and enrollment workflows improves efficiency and effectiveness across any whole person care project. Requiring procured government benefit systems (accessible via website or app) to make their systems available via APIs would reduce duplicate data entry for people applying for multiple programs, within or across multiple agencies.

## Why Do We Need the NDH to Serve as an AI Trust Registry?

What are the differences between old narrow AI, modern large language model (LLM) approach to AI and AI Agents?

While a comprehensive analysis of the different types of AI/Machine Learning is beyond the scope of this RFI response, there are three broad factors/clarifications that have significant ramifications for policymakers.

- **Modern AI Performance** - Most Widely Used AI models (e.g. Claude, ChatGPT, Gemini etc.) are Large Language Models (LLMs) that are outperforming AIs that were developed for narrow specific tasks. These improvements are clear in a wide range of tasks (e.g. language generation, semantic similarity, classification, translation etc.)
- **Uneven Performance & Interpretability** – For any given AI Model, performance on any task can vary over time based on the quality of data used to train it on that task, and performance can differ for different populations due to the circumstances of their lives.
- **AI Agent** – While there are many different definitions of AI Agents/Agentic AI, for the purposes of this RFI AI agents are a type of AI that (a) may facilitate data collection and exchange across different systems, (b) has the capability to perform a wider variety of actions/or tasks and thus greater risks, (c) may need to interact with other AI agents, or members of a patient's care team.

Modern technology can put a man on the moon and track real-time data on individual patient health that drives both immediate care decisions and population-wide health initiatives. Yet:

**policymakers at the highest levels of government lack real-time data on the “health” of our healthcare AI ecosystem and data exchange ecosystems.**

Neither anecdotes nor statistics on TECCA participation tell us whether AI systems are helping or harming patients at scale. We see dramatic improvements of AI performance on healthcare benchmarks, and hypothetical, patients that resemble real world patients.

Yet we lack consistent data on physician errors. When researchers have it, that data is not disaggregated by whether that is because of human error, or because the human accepted the advice of the Clinical Decision Support algorithm, or because the clinician did refuse the advice of the algorithm. The NDH should evolve to support a modern data exchange infrastructure. An AI Security Framework for Healthcare could help to save lives, improve health outcomes, reduce costs, and speed the adoption of impactful AI.

# AI Security Framework for Healthcare: National Directory Implementation

## Understanding the Challenge

As healthcare increasingly relies on AI-powered systems to coordinate care, analyze population health data, and support clinical decisions, we face a critical question: How do we ensure these AI systems operate safely and responsibly while still enabling the innovation that can improve patient outcomes and reduce costs?

The National Directory of Healthcare Providers & Services (NDH) presents a unique opportunity to address this challenge by evolving from a simple provider directory into a comprehensive AI Trust Registry—a system that verifies, monitors, and coordinates AI applications across the healthcare ecosystem.

The National Directory of Healthcare Providers & Services (NDH) presents a unique opportunity to address this challenge by evolving from a simple provider directory into a comprehensive AI Trust Registry—not by replacing existing security systems, but by serving as the coordination layer that enables existing security frameworks to work together effectively.

Rather than replacing organizations' preferred security tools, the NDH would capture audit logs, translate data governance rules into machine-readable formats, and "direct traffic" by telling AI systems which security protocols are required for different healthcare endpoints. Think of it as a sophisticated routing system that ensures AI agents follow the right security rules when connecting to different healthcare organizations, while those organizations maintain full control over their own security infrastructure.

The NDH could also make its coordination logs available to other security monitoring systems, creating redundancy and enabling organizations to use their preferred security analytics tools while participating in the broader trust ecosystem.

## Security Risks When AI Agents Access Healthcare Data

### 1. Data Collection Beyond Intended Purpose

**The Problem:** Unlike human staff who understand context and boundaries, AI systems can systematically collect and transmit sensitive patient data without recognizing when they're overstepping their intended role.

**Real-World Example:** An AI system designed to help coordinate diabetes care might end up collecting detailed mental health records, financial information, or other sensitive data that isn't necessary for its specific function.



**NDH Solution:** The National Directory could maintain detailed records of exactly what data each verified AI system is authorized to access, creating clear boundaries that prevent this type of data overreach.

## **2. Unauthorized System Access**

**The Problem:** Once an AI system gains access to one part of a healthcare network, poorly configured systems might allow it to access other systems and data far beyond what was originally intended.

**Real-World Example:** An AI system authorized to access appointment scheduling data might potentially gain access to billing systems, clinical records, or other sensitive areas if proper security boundaries aren't maintained.

**NDH Solution:** By mapping the complex relationships between healthcare providers, organizations, and systems, the National Directory could specify exactly which AI systems can access which networks and under what circumstances.

## **3. Persistent Access Credentials**

**The Problem:** AI systems need to operate continuously without human intervention, which means they require long-term access credentials that become attractive targets for malicious actors.

**Real-World Example:** Rather than logging in each time like a human user, an AI system might have stored credentials that, if compromised, could provide unauthorized access to healthcare systems for extended periods.

**NDH Solution:** The Directory's existing verification framework could be extended to regularly validate AI system credentials and automatically revoke access when security concerns arise.

# **Building Trust Through the National Directory Framework**

## **AI Trust Registry Capabilities**

The National Directory data standard already envisions many functions that could be extended to create a comprehensive AI Trust Registry:

### **Verification and Credentialing:**

Just as the NDH currently envisions the verification of provider licenses and credentials against authoritative sources, it could verify that AI systems meet specific security, privacy, and ethical standards before they're granted access to healthcare data.

## Relationship Mapping for Machine Discoverable AI Governance

The Directory already is envisioned to track complex relationships between providers, organizations, and insurance networks. This capability could be extended to specify which AI systems are authorized within different healthcare networks and what permissions they have.

### Endpoint Discovery:

Healthcare organizations could use the Directory to advertise their AI interaction capabilities and requirements, making it easier for authorized AI systems to connect while maintaining security boundaries.

## Federated Security Approach

Rather than mandating one-size-fits-all security requirements, the National Directory could enable a federated approach where:

- **Different healthcare networks maintain their own AI security frameworks** while using the NDH to communicate their requirements and compatibility
- **Organizations keep their preferred security tools** while ensuring they can work together across the healthcare ecosystem
- **Graduated trust levels** allow routine administrative AI systems broader access while requiring additional verification for AI systems involved in clinical decision-making

In a staging environment, the NDH could facilitate systems that meet security requirements.

## Operational Security Through the National Directory

### Comprehensive Monitoring and Audit Trails

#### Behavioral Monitoring:

The Directory could track AI system behavior patterns across the healthcare network, identifying when systems deviate from expected activities. This might include monitoring data access patterns, system resource usage, and communication behaviors.

#### Audit Trail Creation:

Every AI system interaction could be logged through the NDH, creating a comprehensive record of which AI systems accessed what types of data, for what purposes, and with what safeguards in place.

### **Automated Compliance Reporting:**

As AI governance requirements emerge, organizations could demonstrate adherence across their healthcare systems through standardized reporting facilitated by the Directory.

### **Policy-Based Access Control**

#### **Dynamic Permission Management:**

Unlike static provider credentials, AI system permissions may need frequent updates based on performance, compliance status, or changing organizational policies. The NDH's notification framework could support real-time permission updates across the network.

#### **Use Case-Specific Authorization:**

The Directory could specify which AI capabilities are authorized for different healthcare use cases (such as provider credentialing, quality reporting, or care coordination), what data minimization requirements apply, and what human oversight is required.

## **Advancing Innovation and Security: Implementation Benefits**

### **For Policymakers and the Ecosystem**

#### **Advancing AI Innovation and Security Through System-Wide Learning**

The challenge lies in implementing security controls that don't undermine AI system effectiveness while enabling the healthcare ecosystem to collectively learn and improve AI governance. The National Directory approach addresses this through a fundamentally different model that transforms compliance from a static burden into a dynamic learning system.

#### **Machine-Readable Security Standards as Open Data Infrastructure**

Rather than mandating specific security technologies, the NDH would enable organizations to publish their AI governance requirements in standardized, machine-readable formats. This likely requires evolution of existing open data standards—potentially extending FHIR resources or developing new standards specifically for AI governance metadata.

Think of it as creating a "security API" for healthcare AI: an AI system could query the NDH to understand not just what data it can access, but exactly what security protocols, audit requirements, and behavioral constraints apply for different types of healthcare interactions. Organizations would publish their requirements in these standardized formats, allowing AI systems to automatically configure themselves for compliant operation across different healthcare networks.

## Collective Intelligence for AI Governance Evolution

The NDH's most innovative aspect would be its role in creating system-wide learning about AI governance effectiveness. By collecting standardized audit logs, behavioral patterns, and outcome metrics from across the healthcare ecosystem, the Directory would enable participants to collectively improve their AI governance approaches.

For example, if certain AI behavioral monitoring techniques prove more effective at preventing data overreach while maintaining system performance, that intelligence could be shared (in aggregate, privacy-preserving ways) across the network. Healthcare organizations could see how their AI governance approaches compare to industry benchmarks and identify opportunities for improvement.

## Real-Time Governance Adaptation

This system-wide learning enables something unprecedented: real-time adaptation of AI governance based on collective experience. Rather than waiting for regulatory updates or industry guidelines, the NDH could facilitate rapid sharing of effective governance innovations. When new AI risks emerge or new mitigation strategies prove effective, the standardized data formats would allow rapid propagation of these insights across the healthcare ecosystem.

## Research Infrastructure for AI Effectiveness

The NDH would also serve as critical infrastructure for AI effectiveness research. By maintaining standardized logs of AI system performance, security incidents, and governance interventions, the Directory would enable researchers to study questions like:

- Which AI governance approaches best balance security with clinical effectiveness?
- How do different monitoring strategies affect AI system learning and adaptation?
- What are the early warning signs of AI systems exceeding their intended scope?

This research capability would accelerate the development of more effective AI governance approaches while providing evidence-based guidance for policy development.

## Graduated Trust Through Demonstrated Performance

The "graduated access models" would work through this data-driven approach: AI systems would earn broader permissions by demonstrating compliance and effectiveness through the standardized metrics captured in the NDH. Rather than relying on static credentials, trust would be based on verifiable performance data, creating incentives for AI developers to build more trustworthy systems.

This transforms AI governance from a compliance checkbox into a competitive advantage, where better governance leads to broader access and more effective AI systems.

## Privacy-Preserving Analytics

The National Directory could enable AI systems to perform valuable population health analysis while protecting individual privacy through:

### Federated Query Systems

AI systems could request aggregate, de-identified insights about population health patterns without ever accessing individual patient records. The Directory would coordinate these requests across multiple healthcare organizations.

### Differential Privacy Protocols

When AI systems need population-level insights (such as diabetes prevalence in a geographic region), the Directory could orchestrate queries to multiple providers, with each organization adding statistical "noise" to protect individual privacy while maintaining overall accuracy.

## Implementation Benefits

### For Healthcare Organizations

#### Reduced Security Management Burden:

While organizations would retain full control of the security framework and responsibility for the systems they procure they could optionally reduce required vetting of every AI system, organizations and rely on Directory verification

#### Improved Interoperability:

Standardized AI interaction protocols would make it easier to work with AI systems across different healthcare networks, governments, Managed Care Organizations and other actors

#### Enhanced Compliance:

Automated audit trails and compliance reporting would reduce administrative burden. Healthcare organizations would remain in control of their compliance and security stack while optionally benefiting from NDH audit and compliance services.

### For AI Developers & AI Agents

#### Clear Security Requirements:

Developers and AI Agents would know exactly what security standards they need to meet for different types of healthcare applications

## **Streamlined Procurement Process and Security Redundancies when Desired:**

Verified AI systems could more easily connect with healthcare organizations across the ecosystem, and Technical Leadership could have guidance and greater trust in verified AI systems

### **Reduced Development Costs**

Standardized interfaces would reduce the need to create custom integrations for each healthcare organization

## **For Patients and the Healthcare System**

### **Enhanced Privacy Protection:**

Comprehensive monitoring and audit trails would provide stronger privacy protections than current ad-hoc approaches.

### **Improved Care Coordination:**

Trusted AI systems could better coordinate care across different providers and organizations, while improving access to proven programs that drive better health outcomes and reduce healthcare costs.

### **Innovation Acceleration:**

A trusted infrastructure would enable more rapid development and deployment of beneficial AI applications and personalized medicine that drive better outcomes.

The National Directory of Healthcare Providers & Services represents a unique opportunity to create the trust infrastructure necessary for safe, effective AI deployment in healthcare. By extending its existing verification, relationship mapping, and endpoint discovery capabilities, the NDH could become the foundation for a comprehensive AI Trust Registry that enables innovation while maintaining the security and privacy protections that healthcare demands.

This approach would transform the NDH from a provider directory into a comprehensive trust infrastructure supporting both human-driven and AI-driven healthcare data exchange, while maintaining the flexibility for organizations to implement their preferred security frameworks within a coordinated ecosystem.

# Regulatory Compliance as Commodity Infrastructure

## The HHS "Other Pocket Problem": When Compliance Costs Undermine Program Goals

Across HHS's 100+ programs, a fundamental problem undermines policy effectiveness: compliance costs often consume resources that could otherwise serve beneficiaries. When a Community Health Center spends \$50,000 annually on duplicative reporting to CDC, CMS, HRSA, and ACL—covering substantially the same population health data—those resources can't hire community health workers who deliver 2.5:1 ROI in preventing costly hospital admissions.

This represents the "other pocket problem" at scale: HHS agencies optimize their individual compliance requirements without considering the cumulative burden on the organizations actually delivering services. The result is a system where compliance costs can exceed program benefits, particularly for smaller Community-Based Organizations serving the most vulnerable populations.

## The National Directory as Policy Analysis Infrastructure

The National Directory of Healthcare Providers & Services, reimagined as a Data Exchange Operating System, offers a unique solution: transforming compliance from a cost center into infrastructure that generates policy intelligence while reducing administrative burden.

### Real-Time Policy Impact Assessment

Rather than waiting years for program evaluations, the NDH could provide real-time visibility into how regulatory changes affect service delivery. When CMS updates Medicaid eligibility requirements or CDC modifies public health reporting standards, the standardized data flows through the NDH would immediately reveal:

- Which Community-Based Organizations face increased compliance burden
- How compliance costs affect service capacity in different geographic regions
- Whether new requirements create barriers for organizations serving specific populations
- What technical assistance or policy modifications could maintain compliance while preserving service delivery

This transforms policy development from educated guesswork into evidence-based iteration, enabling HHS to optimize regulations for maximum program effectiveness rather than maximum compliance documentation.

## **Cross-Agency Coordination Through Shared Infrastructure**

The NDH's most powerful capability would be enabling different HHS agencies to share compliance infrastructure while maintaining their distinct programmatic focus. Consider a Community Care Hub serving older adults with multiple chronic conditions:

**Current State:** Separate reporting to CDC (chronic disease surveillance), CMS (Medicare quality measures), ACL (aging services data), and HRSA (health professional shortage area data), each requiring different data formats, submission timelines, and technical systems.

**NDH-Enabled State:** Single data submission in FHIR format that automatically generates required reports for each agency while enabling cross-program analysis of intervention effectiveness.

This shared infrastructure approach could reduce compliance costs by 60-80% based on similar standardization initiatives, while improving data quality through elimination of duplicate entry and format translation errors.

## **AI-Driven Compliance: Making Regulatory Adaptation Approach Zero Marginal Cost**

The NDH's AI Trust Registry capabilities extend beyond security to enable "regulatory rules as code" that can adapt to policy changes with minimal organizational burden.

### **Automated Policy Translation**

When HHS agencies update program requirements, AI systems could automatically translate new regulations into machine-readable compliance requirements. Community-Based Organizations using NDH-compliant systems would receive automatic updates to their data collection and reporting processes, rather than spending months interpreting new requirements and modifying their systems.

France's OpenFisca platform demonstrates this capability at national scale, managing social benefits calculations for millions of citizens through machine-readable policy rules. When policy changes occur, the updates propagate automatically across all implementing systems. A similar approach for HHS programs could eliminate the 6-12 month lag time between policy updates and effective implementation.

### **Policy Sandbox for Evidence-Based Regulation**

The NDH could enable HHS agencies to test regulatory changes before full implementation, similar to the UK Financial Conduct Authority's "always open" regulatory sandbox. Small pilot implementations could reveal unintended consequences or identify more effective approaches before imposing costs across thousands of organizations.



For example, before implementing new social determinants of health reporting requirements across all Federally Qualified Health Centers, HHS could pilot the requirements with volunteer organizations through the NDH framework. Real-time data on compliance costs, data quality, and program outcomes would inform the final policy design.

## **Policy Iteration Speed: Enabling Rapid Regulatory Improvement**

Traditional regulatory processes assume that compliance infrastructure must be rebuilt with each policy change. The NDH approach enables rapid policy iteration by separating the infrastructure (standardized data exchange) from the specific requirements (which programs need what data, when, and in what format).

### **The Community Health Integration (CHI) Code Example**

CMS's new Community Health Integration codes represent exactly this type of infrastructure investment. Rather than requiring Community-Based Organizations to develop entirely new billing and documentation systems, the CHI codes leverage existing healthcare payment infrastructure while enabling new types of community-based interventions.

The NDH could extend this approach across all HHS programs: standardized infrastructure that enables policy innovation without imposing technology rebuild costs on service providers. When research shows that certain community health worker interventions are particularly effective for diabetes management, policy could be updated to encourage those interventions without requiring organizations to modify their core systems.

### **Cross-Sector Learning and Adaptation**

The NDH's data standardization would enable HHS to identify successful approaches in one program and rapidly test them in others. If ACL-funded Area Agencies on Aging develop effective approaches to medication adherence for older adults, those approaches could be quickly piloted in CMS Medicare programs or CDC chronic disease prevention initiatives.

This cross-program learning capability could accelerate the adoption of effective interventions while reducing the risk of scaling approaches that don't work in different contexts.

## **Addressing the "Other Pocket Problem" Through Aligned Incentives**

The fundamental policy challenge is aligning compliance requirements with program outcomes. The NDH framework creates several mechanisms to address this:

## Outcome-Based Compliance Metrics

Rather than measuring compliance through documentation volume, the NDH could enable outcome-based compliance assessment. Community-Based Organizations would be evaluated on their success in improving health outcomes, increasing benefit enrollment, or reducing emergency department utilization—with documentation requirements automatically generated from routine service delivery data.

## Shared Investment, Shared Savings

HHS agencies could pool their compliance and evaluation budgets to fund shared NDH infrastructure, with savings distributed based on each agency's historical compliance costs. This creates incentives for agencies to reduce compliance burden while maintaining program integrity.

## Technical Assistance as Infrastructure

The NDH could transform technical assistance from ad-hoc support to embedded infrastructure. When organizations struggle with compliance requirements, AI systems could automatically identify the specific challenges and connect them with relevant resources or policy modifications.

## Implementation Through Existing Infrastructure

The NDH approach builds on existing HHS investments rather than requiring entirely new systems:

- **FHIR Standards:** Already mandated for healthcare interoperability, FHIR provides the foundation for standardized social services data exchange
- **TEFCA Framework:** The Trusted Exchange Framework creates the legal and technical foundation for secure data sharing across organizational boundaries
- **Existing Agency Systems:** Rather than replacing agency-specific systems, the NDH would serve as the translation layer enabling interoperability

This incremental approach could demonstrate value quickly while building toward more comprehensive transformation over time.

## Conclusion: Dual Savings via Automated Compliance & Policy Intelligence → Smart Program Investments

The National Directory's evolution into regulatory compliance infrastructure would transform the relationship between HHS programs and the organizations that implement them. Rather than imposing compliance costs that compete with service delivery, standardized infrastructure would

automate reporting and generate policy intelligence that improves program effectiveness while reducing administrative burden. The blowback the White House has experienced with DOGE is partially because federal and state governments do not have the infrastructure to evaluate the impact of cancelling many programs. An NDH, properly designed and governed, could align incentives across HHS programs when Agency A's investment led to savings in Agency B. This creates the foundation for more effective, more efficient, and more responsive government programs that improve outcomes for the populations they serve, while also reducing costs.

## **Governance Framework for the National Directory**

### **Beyond Traditional Federal Models: A Federated Trust Network**

The National Directory of Healthcare Providers & Services requires a governance structure that reflects the reality of American healthcare delivery: a complex ecosystem of federal, state, local, and private sector actors, each with legitimate autonomy needs while serving interconnected populations. Rather than imposing top-down federal control, the NDH governance model should enable coordinated action while preserving the decision-making authority that different sectors require to serve their communities effectively.

### **Public-Private Partnerships with Community-Based Organizations as Full Partners**

#### **Recognizing CBOs as Essential Infrastructure**

Community-Based Organizations represent the "last mile" of healthcare delivery, particularly for populations with multiple chronic conditions who drive 67% of healthcare costs. Yet current healthcare governance structures often treat CBOs as vendors or subcontractors rather than partners with unique expertise and community accountability.

The NDH governance framework should establish CBOs as full partners in the trust network, with representation proportional to their role in actual service delivery. This means:

**Direct CBO Representation:** Community-Based Organizations would have voting representation on NDH governance bodies, not just advisory roles. This ensures that compliance requirements and data standards reflect the operational realities of organizations actually delivering services to vulnerable populations.

**Capacity Building Investment:** Rather than expecting CBOs to absorb the costs of participating in standardized data exchange, the governance framework should include dedicated funding streams for CBO technology infrastructure, training, and ongoing support. This investment recognizes that effective governance requires capable participants.

**Community Accountability Integration:** The governance structure should incorporate mechanisms for community input on data use and privacy policies, ensuring that the populations most affected by data sharing decisions have meaningful voice in governance decisions.

## **Private Sector Innovation Within Public Interest Framework**

Healthcare technology companies, Electronic Health Record vendors, and cloud infrastructure providers are essential partners in creating the technical infrastructure for the NDH. However, their participation must be structured to serve public interest goals rather than primarily extracting value from public data.

**Open Standards Requirements:** Private sector participants would be required to implement open, interoperable standards rather than proprietary systems that create vendor lock-in. This ensures that public investment in the NDH creates public value rather than private competitive advantages.

**Data Portability Guarantees:** Organizations using NDH infrastructure would retain full rights to their data and the ability to move between different technology providers. This prevents the creation of data monopolies while encouraging innovation among competing providers.

**Shared Value Creation:** Private sector participants could generate revenue from value-added services and efficiency improvements, but the core NDH infrastructure would be treated as a public utility with appropriate governance oversight.

## **Decentralized Decision-Making for Sector-Specific Requirements**

### **Healthcare vs. Social Services: Different Missions, Different Governance Needs**

Healthcare providers operate under HIPAA privacy requirements, clinical quality standards, and medical malpractice liability frameworks that don't directly apply to social service organizations. Conversely, Community-Based Organizations serving housing, nutrition, or employment needs operate under different federal funding requirements, community accountability structures, and outcome measurement systems.

The NDH governance framework should enable sector-specific governance councils that can adapt the overall framework to their distinct requirements:

**Clinical Data Governance Council:** Healthcare providers, health plans, and clinical researchers would govern the use of clinical data within the NDH, ensuring compliance with HIPAA, FDA requirements, and clinical research standards.

**Social Services Governance Council:** CBOs, Area Agencies on Aging, social service departments, and community advocates would govern social determinants data sharing, ensuring compliance with various federal social service program requirements while preserving community accountability.

**Cross-Sector Coordination Council:** Representatives from each sector-specific council would coordinate on issues affecting multiple sectors, such as whole-person care coordination and population health analytics.

## **AI Governance Tailored to Use Cases**

Different applications of AI within the healthcare ecosystem require different governance approaches:

**Clinical Decision Support AI:** Subject to FDA oversight, clinical evidence requirements, and medical malpractice standards, with governance focused on patient safety and clinical effectiveness.

**Administrative Automation AI:** Focused on efficiency and accuracy in tasks like eligibility verification, appointment scheduling, and benefits enrollment, with governance emphasizing privacy protection and bias prevention.

**Population Health AI:** Used for community health planning, resource allocation, and outcome measurement, with governance involving community stakeholders and emphasizing equity and community benefit.

This differentiated approach ensures that AI governance is proportional to risk and appropriate to context, rather than imposing uniform requirements that may be excessive for low-risk applications or insufficient for high-risk ones.

## **Federated State Implementation: Local Control with National Interoperability**

### **States as Primary Implementation Partners**

Rather than creating a centralized federal system, the NDH should be implemented through state-level partnerships that preserve state authority over healthcare delivery while enabling nationwide interoperability.

**State NDH Instances:** Each state would maintain its own copy of the National Directory, containing complete data about providers, organizations, and services within the state, plus the minimum dataset necessary for cross-state coordination.

**State Governance Authority:** States would have authority to set additional requirements for organizations operating within their borders, provided they maintain compatibility with the national minimum dataset and interoperability standards.

**Interstate Coordination Mechanisms:** When patients receive care across state lines or when multi-state organizations need to coordinate services, standardized protocols would enable seamless data sharing while respecting each state's governance requirements.

## **Minimum Dataset Definition and Evolution**

The national minimum dataset would include only the information necessary to enable basic interoperability and coordination:

**Provider Identity and Credentials:** Basic information needed to verify provider licenses, credentials, and organizational affiliations across state lines.

**Service Availability:** Standardized descriptions of services offered, accessibility information, and capacity data needed for referral and care coordination.

**Endpoint Information:** Technical information needed to enable secure data exchange between organizations in different states.

**Quality and Outcome Metrics:** Standardized measures needed for comparative analysis and quality improvement, while allowing states to add additional measures that reflect their specific priorities.

## **Local Innovation with National Learning**

This federated approach enables states to serve as laboratories for governance innovation:

**Policy Experimentation:** States could test different approaches to AI governance, data sharing policies, or quality measurement, with successful innovations shared across the network.

**Regulatory Alignment:** States could align their healthcare regulations with NDH standards at their own pace, reducing compliance burden for organizations operating across multiple jurisdictions.

**Resource Sharing:** States could pool resources for technical infrastructure, training, and support while maintaining autonomous decision-making authority.

## **Accountability and Oversight Mechanisms**

## Multi-Stakeholder Governance Board

The NDH would be governed by a multi-stakeholder board representing all major participant categories:

- **Federal Agencies:** HHS agencies (CMS, CDC, ACL, HRSA) that rely on NDH data for program administration
- **State Government:** Representatives from state Medicaid agencies, public health departments, and aging services networks
- **Healthcare Providers:** Hospitals, health systems, primary care practices, and specialty providers
- **Community-Based Organizations:** Representatives from different types of CBOs serving diverse populations
- **Technology Partners:** EHR vendors, cloud providers, and healthcare technology companies
- **Community Advocates:** Representatives from disability rights, aging advocacy, and health equity organizations

## Transparent Decision-Making Processes

All governance decisions would be made through transparent processes with public input opportunities:

**Open Meetings:** Governance board meetings would be public with opportunities for community input on major decisions.

**Public Comment Periods:** Proposed changes to data standards, privacy policies, or governance structures would be subject to public comment with responses published.

**Impact Assessments:** Major policy changes would require assessments of impact on different participant types, with particular attention to effects on smaller CBOs and vulnerable populations.

## Performance Accountability

The governance framework would include specific accountability mechanisms:

**Outcome Reporting:** Regular public reporting on NDH performance metrics, including cost savings, service coordination improvements, and equity outcomes.

**Independent Auditing:** Regular third-party audits of data security, privacy compliance, and governance effectiveness.

**Community Feedback Mechanisms:** Structured processes for communities served by NDH participants to provide feedback on data use and governance decisions.

# **Implementation Pathway**

## **Phase 1: Core Infrastructure and Early Adopters**

Begin with willing state partners and established healthcare systems to demonstrate the federated governance model while building core technical infrastructure.

## **Phase 2: CBO Integration and Cross-Sector Expansion**

Add Community-Based Organizations and social service agencies as full partners, with dedicated support for capacity building and governance participation.

## **Phase 3: AI Governance Integration**

Implement the AI Trust Registry components with sector-specific governance councils managing AI applications appropriate to their domains.

## **Phase 4: Full Federation**

Complete the transition to state-based NDH instances with full interoperability and shared governance across all participant sectors.

# **Governance as Infrastructure for Innovation**

This governance framework recognizes that effective coordination requires both shared standards and local autonomy. By creating infrastructure that enables cooperation without mandating uniformity, the NDH can serve as a platform for innovation while preserving the diversity and community accountability that make American healthcare and social services responsive to local needs.

The ultimate goal is governance that enhances rather than constrains the ability of healthcare providers, Community-Based Organizations, and other essential partners to serve their communities effectively—creating the foundation for better health outcomes and more efficient resource use across the entire healthcare ecosystem.

## **A National Directory Proof of Concept Open City Labs Unified Infrastructure**

Open City Labs executive team has been heavily involved in the development of the HL7 FAST FHIR National Directory for Healthcare Providers and Services, and was amongst the first to demonstrate National Directory standards alignment at the July 2022 CMS Connectathon. In a



subsequent CMS HL7 Connectathon we successfully demonstrated with other vendors how FHIR-based directory infrastructure could enable long term post acute care referrals for patients needing transportation services that support wheelchairs, automated eligibility screening across government programs, real-time referral coordination between healthcare and social services, and government benefits like SNAP. Our subsequent victory in the Administration for Community Living Social Care Referrals Challenge Grand Prize and Bonus Prize wins proved these concepts could scale across the complex ecosystem of healthcare and social service providers.

Today, as AI capabilities rapidly advance and healthcare data exchange becomes increasingly critical to care quality and cost containment, the National Directory represents more than directory management—it's the foundation for a Data Exchange Operating System for healthcare interoperability. This system wouldn't replace existing technologies or centralize control, but rather provide the standardized infrastructure that enables thousands of organizations to build better solutions while maintaining their autonomy and competitive advantages.

The question facing HHS isn't whether to invest in interoperability infrastructure, but whether to build it strategically as a platform that enables innovation across all programs and sectors, or continue the current approach of fragmented, program-specific solutions that multiply costs while limiting capability. The National Directory offers a path toward the former: infrastructure that makes regulatory compliance predictable, AI development trustworthy, and citizen services as intuitive as any modern digital platform.

# RFI Question Reference Index

*(Clean appendix mapping each RFI question ID to corresponding sections)*

## Innovation, Accountability, and Competition

What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?

PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?

## 2. Data Access and Integration

a. What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?

A core principle of good governance is, if you can avoid it, don't make someone enter data that they have already done. If giving people access to the data they enter into a patient portal or government form, and preventing duplicate data entry, how would we think about solving this problem from a technology, data standards, regulatory and procurement perspectives.

b. What are specific sources, other than claims and clinical data, that would be of highest value, and why?

Providing access to data entered into forms like Medicaid, Medicare, SNAP, WIC, and other eligibility and enrollment forms. Reusing healthcare data, so that it can inform eligibility and enrollment, enabling apps to proactively inform people of their eligibility.

c. What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?

**From Section B. Patients and Caregivers:**

PC–1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, and the actions you should take?

a. What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?

PC–4. What features are missing from apps you use or that you are aware of today?

a. What apps should exist but do not yet? Why do you believe they do not exist yet?

PC–9. Given that the Blue Button 2.0 API only includes basic patient demographic, Medicare coverage, and claims data (Part A, B, D), what additional CMS data sources do developers view as most valuable for inclusion in the API to enable more useful digital products for patients and caretakers?

a. What difficulties are there in accessing or utilizing these data sources today?

**From Section E. Technology Vendors, Data Providers, and Networks:**

TD–1. What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?

TD–2. Regarding CMS Data, to stimulate developer interest—

a. What additional data would be most valuable if made available through CMS APIs?

b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?

c. What obstacles prevent accessing these data sources today?

d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?

TD–4. How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?

TD–5. How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?

TD–7. [USCDI] To what degree has USCDI improved interoperability and exchange and what are its limitations?

a. Does it [USCDI] contain the full extent of data elements you need?

TD–13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient’s electronic health information (EHI)?

a. What are the primary obstacles to this?

b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?

TD–16. What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?

a. Do current rules encourage scalable network participation?

b. What changes would improve alignment (for example, API unification, reciprocal access)?

VB–15. How could a nationwide provider directory of FHIR endpoints help improve access to patient data and understanding of claims data sources? What key data elements would be necessary in a nationwide FHIR endpoints directory to maximize its effectiveness?