Draft Health Data Utility (HDU) Framework Supplement Version 1

FOR PUBLIC FEEDBACK

CIVITAS
Networks for Health

Guidance for Comments

Civitas Networks for Health (Civitas) has released this Draft HDU Framework Supplement Version 1 for public feedback. Civitas is seeking stakeholder and community partner input online through January 31, 2025. The public may provide input through the form linked here, or via email to hdu@civitasforhealth.org. This Supplement accompanies the previously released Health Data Utility Framework, which can be found at www.civitasforhealth.org/health-data-utilities and here in PDF format. We welcome feedback on both the original Framework and the Supplement.

Given the unique health data and health improvement landscape in each state and region, Civitas hopes that stakeholders will provide input on the usefulness of the Supplement and help us to identify what is missing from this resource. Please consider what would be helpful while assessing the current health data ecosystem within your geography, or if you are beyond assessment and in a planning phase, share what else may be useful. This resource is intended for health data ecosystem partners within a defined geographic area that aim to either establish an HDU or who are working to advance their existing model.

After the comment period closes on January 31, 2025, the Civitas team will review and revise the resource and plan to publish the Supplement during the first quarter of 2025. At this time, we will host an informational webinar.

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Overview

Delivering high-quality, comprehensive care requires access to complete health and social care data to enhance outcomes, reduce disparities, and foster patient trust. Over the past two decades, federal, state, and private investments in health data infrastructure have enabled better communication and care coordination through interoperable platforms. As a result of these efforts, most states have established statewide or regional Health Information Exchange (HIE) networks that link diverse electronic health record (EHR) systems across inpatient, outpatient, and community care settings. These HIE networks have become essential for promoting whole-person care and driving value-based health system transformation by integrating clinical and non-clinical data from hospitals and health care settings, payers, public health authorities, social services agencies, and community-based organizations.

The continued expansion of electronic health and social care data exchange and use support broader clinical and public health objectives. By leveraging combined clinical and non-clinical datasets, establishing new partnerships, and deploying advanced data tools, states are advancing their health data governance models through designated organizations and networks. This evolution is exemplified by the Health Data Utility (HDU) model, which serves as a reusable framework for safe, secure, and appropriate health information exchange and data aggregation supporting value added services which are responsive to the priorities of public health authorities, providers, and community stakeholders.

Civitas released the first HDU Framework in March 2023 thanks to the generous support of the Maryland Health Care Commission. The Framework has led to increased attention to the HDU model, and helped clarify key aspects of the model such as naming characteristics and necessary factors. It has helped to establish HDU as an effective framework for states and regions to assess their health data exchange landscape, moving HDU from concept to practice by supporting partners in various phases of implementation.

What are HDUs?

HDUs operate as neutral entities and/or networks, often structured as nonprofits or independently governed organizations with state recognition or designated authority for health data technical implementations, providing technical services and reusable technical infrastructure. HDU technical infrastructure and services are flexibly designed to serve diverse stakeholders, including public health agencies, health care providers, payers, quality improvement and accountable care organizations, community partners, and academic researchers.

HDUs should have a specific geographic scope and service area, such as an entire state or region, with alignment to public health jurisdictions. Geographic breadth allows HDUs to collect and exchange data from a diverse set of sources while also accommodating many different types of use-cases (including and outside of local needs), such as population health management, quality improvement, or public health reporting in emergent and non-emergent times.

HDUs are generally formed with a clear mandate from states, often created by the state through legislation, executive orders, or other formal mechanisms. This designated authority and scope leverages a multi-stakeholder governance model with defined decision-making processes and accountability mechanisms. Community stakeholders and partners include public and private sector entities (e.g., health care providers, payers, government agencies and community

organizations) which work collaboratively through the HDU to improve interoperability and service integration in a way that best meets their common needs and objectives. HDUs have a broadened scope for a scalable data ecosystem across the community and statewide, expanding use cases beyond “legacy” point-to-point clinical data exchange.

Health Data Utility (HDU) Reusable Architecture Framework

An HDU is a structured model that provides cooperative leadership, designated authority, and advanced technical capabilities to integrate, enhance, and exchange health data across different care and service settings. This reusable architecture provides comprehensive governance, operational, and technical architecture facilitating treatment, care coordination, quality improvement, and community health initiatives. Whether building on existing HIE infrastructure or defining new data ecosystems from the ground up, states can implement HDUs that meet the broader needs of public health, social care, and other health care stakeholders.

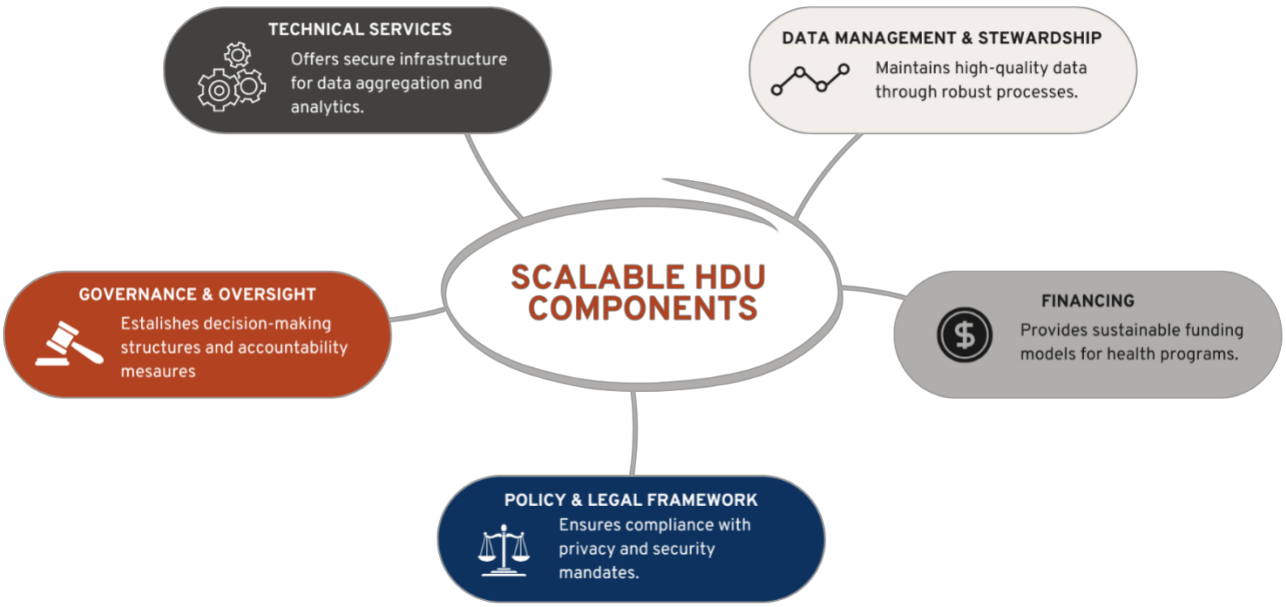
Reusable HDU Components

The following reusable HDU components can enhance scalability, interoperability, and sustainability across a statewide data ecosystem:

1. Governance and Oversight: Clearly defined inclusive decision-making structures, roles and responsibilities, stakeholder engagement, and transparent communications. The multi-stakeholder, cross-sector governance model provides oversight, performance and accountability measurement of network adequacy, and standardized procedures. Reusable Governance component examples include:
    - Governance charter templates
    - Stakeholder engagement frameworks
    - Cross-sector accountability best practices
2. Policy Levers: Maximizing use of public policy levers, reporting requirements, designated authorities, privacy and security mandates, and program compliance. Reusable policy lever examples include:
    - Model legislative templates
    - Regulatory requirements for HDU use, data collection, and exchange standards
    - Policy alignment frameworks mapping HDU services to new and existing programs
    - Creation of new advisory groups, incentives, and mandates
3. Operations and Legal Framework: Utilizing standardized modular data use agreements (DUAs), harmonized privacy and security controls across sectors, and implementation management for new programs and technical services. Reusable operations details include:
    - Statewide DUA templates
    - Legal compliance checks
    - Guidance for multi-party agreements
    - Project management and technical assistance for onboarding and scaling programs
4. Financing: Structured, scalable funding models across federal, state, and private sources that ensure sustainability and usability for a wide range of health priorities and programs serving all populations. Reusable operations details include:

- Business case templates, value propositions, and funding proposals for cross-sector partners
- Partnership frameworks for co-investment
- Transparent funding models for community capacity building

5. Data Management and Stewardship: Clean, matched, normalized, and high-quality data available, with robust processes and systems to maintain and improve upon data quality. Standardized data collection, validation, and storage protocols with feedback loops for continuous improvement, and robust cybersecurity measures. Reusable data management tools include:
    - Data management policy templates
    - Data quality monitoring tools and business practices
    - Security frameworks aligned with industry standards
6. Technical Services and Reusable Infrastructure: Modular, reusable technical infrastructure and technical services for care coordination, data aggregation, and analytics with integrated data sources using industry data and interoperability standards. Reusable technical infrastructure examples include:
    - Modular system architecture, such as Master Person Index (MPI), Provider/resource directory
    - Scalable platforms and technical services using up-to-date and interoperable standards and capabilities



HDU Benefits and Strategic Value

HDUs offer numerous benefits that support both public and private health priorities:

- Federal to State Alignment: HDUs provide a consistent framework for aligning federal, state, regional, and community health data governance policies.
- Standardization Across Intermediaries: HDUs establish and proliferate uniform data and interoperability standards and practices across diverse health and social service organizations reducing the fragmented and siloed approach to digital health. Examples of standardized data use agreements include New York's Statewide Common Participant Agreement or California's Data Exchange Framework.[1,2]
- Reusable Infrastructure: The HDU model leverages existing HIE and state-level data systems, including existing interfaces, data use agreements, and policies, reducing redundancy and optimizing resource use.
- Effective Data Management: HDUs employ sophisticated data management practices, such as validation, de-duplication, and data completeness to ensure high-quality, reliable data for all stakeholders. HDUs do more than transport data between users, they also link and enhance data sets to provide greater insights and longitudinal records.
- Improvements in Health Outcomes and Integrated Data Ecosystem: The growing availability of real-time data and enhanced data analytic tools offers significant benefits for health practitioners, policymakers, researchers, and individuals. Large data sets can enhance different parts of a health system—from policymaking and budget allocations to epidemiological surveillance and clinical research—leading to improvements in prevention, diagnosis, treatment, and care delivery.[3]
- Accountability and Trust: As public or nonprofit organizations with publicly designated authority and multi-stakeholder governance mechanisms, HDUs answer to the people and communities they serve, leveraging existing relationships in their geographies to effectively and consistently provide education and resources on data issues.

The implementation of HDUs strengthens health information governance at the state level, enabling more effective management of health data resources and creating a scalable infrastructure for future health initiatives. HDUs also serve as a unified infrastructure to ease state and federal reporting requirements across health care, public health, and social care programs.

HDU Progress

The landscape of electronic health information exchange across the US has evolved significantly over the past decade. A 2023 Health Affairs article notes that the number of health information exchange organizations (HIOs) decreased from 119 in 2012 to 76 in 2023.[4] This consolidation has resulted in a smaller but more resilient and interconnected network of HIOs that are better positioned to support complex data exchange and meet broader community

[1] https://nyehealth.org/wp-content/uploads/2024/09/SCPA-package.pdf
[2] https://dxf.chhs.ca.gov/
[3] https://www.emerald.com/insight/content/doi/10.1108/IJHG-11-2022-0104/full/html
[4] https://academic.oup.com/healthaffairsscholar/article/2/8/qxae098/7737825

needs. The existing HIOs are leveraging this opportunity to expand their capacity and strengthen their role in statewide health data ecosystems, positioning them as foundational elements for advancing HDU.

The HDU model as it has been articulated by Civitas and other health data stakeholders represents, to a large extent, the culmination of public support and investment in the idea of "public good" health IT functionality since the turn of the century. Virginia passed the first state statute creating a nonprofit health data organization with a "patient-level data system" to collect, share, and analyze information from providers and payers in 1996, the same year that Congress directed the Department of Health and Human Services (HHS) to develop standards and privacy regulations for electronically-transmitted, individually identifiable health information as part of the Health Insurance Portability and Accountability Act (HIPAA).

The advancement of HDU is dependent upon ongoing policy progress and a growing consensus around health data governance standards. Key enablers include:

- Interoperability Policy Developments and Recognition for Local Networks: Policies aimed at promoting seamless data exchange across health and health care entities continue to advance, laying a crucial foundation for HDU adoption. While national networks are critical to advancing interoperability, local networks of health data organizations remain necessary in reaching both underserved providers and harder to reach populations. They are experts in navigating state and local laws and most importantly building trusted community relationships.
- Health Data Governance Roles and Responsibilities: Clearer definitions of roles and responsibilities at state and regional levels have emerged, creating a stronger governance framework for HDU implementation. At the same time, there is greater complexity in the overall governance of health data. As use cases expand, more stakeholders need to be involved in decision making. Having such a framework to guide this process is an asset to states.
- Broader Uptake of Health Data Utility Concepts: There is an increasing uptake of HDU frameworks among states, regions, and organizations as health data organizations respond to increased need for reliable and robust health data. Early adopters are providing a roadmap for others to follow.

As demand for more complete health data and data interoperability became apparent in 2021, and the landscape of health information exchange (HIE) and health improvement was rapidly evolving in the public and private sectors, Civitas Networks for Health (Civitas) and the Maryland Health Care Commission (MHCC) identified the need to differentiate key aspects of emerging Health Data Utility (HDU) models more clearly. CRISP Maryland became the country's first state designated HDU and with this brought increased curiosity about both the HDU model and the necessary factors and market forces to make this a reality. Civitas and MHCC hosted a series of convenings to further explore characteristics and components of the HDU model and to gather broad input from a diversity of stakeholders. From this work, Civitas and MHCC published an in-depth HDU Issue Brief and in 2022 released the first HDU Framework.

HDU Legislative and Policy Levers

The advent of the Health Information and Technology for Economic and Clinical Health (HITECH) Act and its $35 billion total investment in digitization between 2009 and 2021 was a milestone for health information technology in general and HIEs in particular. Much of the funding—approximately $29 billion—was allocated via a "meaningful use" framework that disbursed multi-stage incentive payments for EHR adoption from 2011 onward to Centers for Medicare and Medicaid Services (CMS)-enrolled providers through separate Medicare and Medicaid Promoting Interoperability (PI) programs. Over the same period, HITECH also funneled nearly $3 billion in additional funding directly to states to support health data infrastructure in the form of enhanced 90-10 Medicaid matching dollars for system design, development, and implementation (DDI) and administrative activities tied to meaningful use requirements, as well as ONC grants for workforce training and early-stage HIEs. The latter program included over half-a-billion dollars for cooperative agreements with state-designated public and nonprofit organizations to explicitly "enable the rapid development of health information exchange across the nation."[5]

HITECH's impact was immediate and substantial. By 2012, 44% of hospitals and 40% of office-based physicians were using EHR systems; in 2013, the figures were 59% and 48%; and in 2014 they were 97% and 74% (close to the 96% and 78% achieved when meaningful use incentives sunsetted in 2021).[6] By 2021 nearly 60% of states had also enacted their own laws to promote and accelerate HIE and EHR utilization[7], and all but three states had at least one operational public or nonprofit HIE. Many of these HIEs in turn chose to connect to several nonprofit "networks of networks" that arose with varying degrees of public sanction over the same period (eHealth Exchange, Carequality, CommonWell Health Alliance) to transmit data between state or regional HIEs and combinations of private EHR systems and federal agencies.

By the time the Trusted Exchange Framework and Common Agreement (TEFCA™) launched with partial functionality in late 2023, COVID-19 and its aftermath had catalyzed further evolution among state and regional HIEs whose capabilities played a key role in pandemic response. Before the pandemic, many HIEs were already expanding beyond hospitals and outpatient physicians to long-term care facilities, pharmacies, public and private diagnostic laboratories, and behavioral health clinics. State Medicaid Agency (SMA) linkage became near universal; HIEs also built data sharing partnerships with commercial payers, social service agencies, local and tribal public health departments (to supplement their state PHA presence) and academic researchers. In many cases, state policymakers accelerated these linkages with direct or indirect connectivity mandates. The pandemic period especially underscored the extent to which this integration of both clinical and non-clinical data about patients and communities from a wide range of sources was vital to improving care efficiencies, access, and outcomes.

Policy support has historically played a critical role in fostering data exchange initiatives. In 2014, as part of the Office of the National Coordinator for Health IT (ONC) (now known as the

[5] NORC at the University of Chicago. "Final Report: Evaluation of the State HIE Cooperative Agreement Program." March 2016. Available: https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf
[6] Assistant Secretary for Technology Policy (ASTP). "Health IT Quick Stat #61: National Trends in Hospital and Physician Adoption of Electronic Health Records." Available: https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records
[7] NORC at the University of Chicago. "Final Report: Evaluation of the State HIE Cooperative Agreement Program." March 2016. Available: https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf

Assistant Secretary of Technology Policy (ASTP)) State HIE Cooperative Agreement evaluation, states and grantees enacted legislation promoting HIE participation and EHR adoption. Specifically, 59% of grantees had enacted laws supporting both HIE and EHR adoption, while 36% focused on HIE, and 23% supported both HIE and EHR usage. This policy infrastructure has set the stage for the more mature and technically capable data exchange landscape that is necessary for HDUs to thrive today.

To successfully implement HDUs, states must establish a strong policy and legal framework that supports data sharing and governance. Key policy considerations include:

- Designated Authorities: Establishing clear authority for health data governance, including roles for state agencies, public health authorities, data intermediaries, and community partners.
- Privacy and Security Requirements: Defining and implementing robust privacy and security measures to protect sensitive health data and maintain public trust.
- Program and Compliance Requirements: Ensuring that HDUs meet federal and state program mandates, such as Medicaid data reporting and quality improvement standards.
- Incentives and Mandates: Utilizing policy levers to create incentives for advancing participation and use of the statewide data ecosystem through programs and policies aimed at improving use, scalability, and sustainability.

To successfully implement and sustain HDUs, organizations must focus on making strategic decisions aligned with both community needs and long-term vision, rather than being constrained by historical practices. Strong HDUs are agile, prioritize stakeholder value, health data as a public good, and continuously evolve to meet emerging demands. This forward-looking approach will be crucial for states and regions aiming to advance their HDU capabilities and ensure the continued relevance and impact of their health data systems.

HDU Financing

Multiple financing options exist for funding HDU governance, technical services and infrastructure. HDU-curious states must evaluate how current and developing technical capabilities can continue to serve health policy and programs in the long term through a diversified mix of funding sources that deliver significant return on investment and make the most of available resources. The following funding options are possible funding sources to stabilize, sustain, and grow HDU capacity.

State-based funding through a centralized technology fund built with contributions from payers per member per month (PMPM), provider fee mandates, and/or public health taxes (e.g., tobacco or vape tax). This state health information technology (health IT) fund under the supervision of a new HDU Advisory Board, existing State Health IT Office, or another governing entity could be leveraged to support HDU infrastructure and services, through more direct funding authority and allocation for HDUs. Establishing a health IT fund requires legislation or other policy lever defining decision making, oversight, and accountability metrics. Federal grants could leverage the designation for HDU for directed federal grants and simplified procurement and funding distribution.

CMS Authority Examples

The following examples include potential opportunities for HDU data and infrastructure funding in support of these CMS authorities in cooperation with state Medicaid agencies.

- Section 1903(a)(3) of the Social Security Act: Medicaid Enterprise Systems and Federal Finance Participation (MES FFP)[8]: MES FFP, with the enhanced federal match requires system certification and cost allocation for Medicaid's fair share. MES FFP allows funding to the State Medicaid Agency for data, interoperability, and infrastructure modernization supporting Medicaid programs and populations. This includes support for health-related social needs (HRSN) use cases and platform development. The Center for Medicaid and CHIP Services (CMCS) reviews and approves Advanced Planning Documents (APDs) from Medicaid Agencies at the following enhanced match rates:
    - 90% FFP for planning, design, development, and implementation and 10 percent state match
    - Ongoing 75 FFP for maintenance and operations activities through the modular certification process with 25% state match.[9]
- Section 1115 Waivers and Demonstration Projects[10]: States can apply for waivers to specific federal requirements under sections 1115 and 1915 of the Social Security Act to add flexibility in using federal funds. Through these waivers, states can propose strategic investments and incentive payment programs for meal delivery, case management, service provisioning, and capacity building for care and service delivery integration with data and infrastructure investments. To date, a dozen states have had HRSN service-focused section 1115 waivers approved by CMS under the agency's current (post-2021) guidance, with another four pending.
- Section 1915(c) waivers[11]: State Medicaid Agencies use the Home and Community-Based Services (HCBS) authority to support individuals with disabilities and over 65 who need more intensive support, such as in-home support services, supportive housing, and care management. The 1915(c) waiver provides opportunities to expand data and infrastructure investment with federal matching requirements. To date, 48 of the 50 states (plus D.C.) have at least one active section 1915(c) waiver targeting a wide variety of patient conditions and sub-populations.
- Section 1905(a) State Plan Authority[12]: State Medicaid Agencies can use the State Plan Amendments (SPAs) to specify services Medicaid covers in the state and can focus on SDOH data aggregation, screening, case management, and need-specific support (e.g., housing, employment, and food insecurity). Medicaid Agencies are limited to Federal Medical Assistance Percentage (FMAP), the federal contribution towards Medicaid, based on state per capita income ranging from 50% to an average of 74%.

[8] https://www.medicaid.gov/medicaid/data-systems/health-information-exchange/federal-financial-participation-for-hit-and-hie/index.html
[9] https://www.medicaid.gov/medicaid/data-systems/certification/streamlined-modular-certification/index.html
[10] https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html
[11] https://www.cms.gov/outreach-and-education/american-indian-alaska-native/aian/ltss-ta-center/info/national-overview-1915-c-waivers
[12] https://www.federalregister.gov/documents/2024/05/10/2024-08363/medicaid-program-ensuring-access-to-medicaid-services

Federal Direct Funding, Discretionary Grants, and Cooperative Agreements

Multiple federal agencies direct funding to state and local governments with guidelines on how funds can be used with flexibility in supporting community health initiatives, services, workforce, and technical infrastructure projects to fit the state, locality, or population's needs. Through direct formula funding (e.g., block grants), discretionary grants, and cooperative agreements, federal agencies have multiple authorities to direct funding through designated agencies or entities or through competitive processes that would reuse, grow, or enhance HDU technical architecture and services for broader use. Federal agency examples with potential data and infrastructure funding include:

- Centers for Medicare and Medicaid Innovation (CMMI)
- Center for Medicaid and CHIP Services (CMCS)
- Centers for Disease Control and Prevention (CDC)
- Administration for Strategic Preparedness and Response (ASPR)
- Administration for Children and Families (ACF)
- US Health Resources and Services Administration (HRSA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- US Department of Agriculture (USDA)
- US Department of Housing and Urban Development (HUD)
- US Department of Labor (DOL)
- Administration for Community Living (ACL)
- HHS Office of Minority Health (OMH)

Participant/User Fees: Participant and users of the technical services contribute to the funding through different funding structures.

- Annual or Monthly Membership Fees: Participants pay a recurring fee to be members and access data. This provides a steady revenue stream and simplified billing process. Recurring fees may be a barrier to entry for new participants. Participants will require sufficient value to justify recurring fees.
- Tiered Access Fees: Customizable fee structure for certain types of participants with different needs, budgets, and service needs. Tiered services may enable additional funding for advanced technical or support services. Some HDUs do not charge access to technical services and data for FQHCs, critical access hospitals, or public health.
- Implementation and Onboarding Fees: One-time fees charged to participants for initial set up, training, and integration with HIE technical systems and networks.
- Transaction Fees: Fees charged based on number of records accessed or exchanged, which could be scalable with participant size and capacity. Transaction fees may deter participation due to cumulative costs and would require accurate tracking systems for full transparency.
- Hybrid Versions of Structured Fee Models: Using hybrid funding models combines multiple fee structures based on phase of onboarding or use of new technical services.

Sustainable funding models are crucial for the long-term viability of data collaboration efforts. States need to explore and implement funding mechanisms that ensure the ongoing operation of data infrastructure, support data management and analysis activities, and incentivize participation from all stakeholders.

Value-Added Services

Value-added services are specialized technical service offerings that enhance core data and exchange services. These services aim to improve health care delivery, optimize operations, inform population health metrics, and improve implementation and outcomes. The following list details example services for a broader set of HDU users and networks:

Accountable Care Organizations (ACOs): ACOs and risk-bearing entities focus on delivery of coordinated, high-quality care while managing costs. HDUs can support these business services by providing the following example technical services:

- Data Analytics and Reporting through advanced analytics tools utilizing aggregated health data to generate actionable insights informing performance metrics, trends, and data-driven decisions improving care quality and efficiency. Examples may include Key Performance Indicator (KPI) dashboards, such as readmission rates, patient satisfaction scores, and cost measures.
- Population Health Management tools through technical solutions to aggregate and analyze the health of specific populations and/or disease cohorts and help ACOs identify high-risk patients, monitor chronic disease management, and implement preventive care strategies. Service examples include risk stratification models, cohort analysis tools, and health risk assessments.
- Care Coordination support through HDU tools and services facilitating communication and coordination among care teams and community partners enhancing collaboration and reducing fragmentation across the care continuum. Examples include shared care plans, secure messaging, and single view access to integrated platforms.

Managed Care Organizations (MCOs): MCOs are contracted health plans using manage care model to improve quality of care and providing cost-effective health care services through a capitation payment per member per month. HDUs can support the MCO delivery system by providing the following advanced technical services:

- Utilization Management tools that analyze health care service utilization patterns and inform resource allocation identifying redundant services. Examples include utilization review dashboards or claims data analysis.
- Member Health Monitoring services that track health status and care activities of MCO members facilitating care coordination and outreach efforts. Examples include health trend analysis, chronic disease tracking, and alerts for event notifications or high-risk indicators.
- Data Integration services for HIE data with MCO member records providing a holistic view of member health information from clinical and claims data systems. Examples include integrated data across network partners based on the attributed member list for specific operational and quality measures.
- Provider Network Management through services and tools to help manage, standardize, and optimize the provider network informing provider availability, performance, and data elements. Examples include provider directory services, network adequacy dashboards.

Additional value-added services for public health can be found in the HDU Framework.

Drivers for HDU Adoption

The growing need for robust health data governance and interoperability has been driven by several key federal and state policies, regulations, modernization needs, and industry drivers for health system transformations. The following regulations, waivers, and programs have helped make data ecosystem participation a de facto standard expectation and created an operational framework for information exchange with common rules, technical baselines for health IT developers. The examples below are drivers for the emerging HDU model:

Federal Policies and Regulations

ASTP

- 21st Century Cures Act Final Rule: Health data proliferation was reflected most prominently in Title IV of the 21st Century Cures Act of 2016, which continues to provide the statutory foundation for an ongoing series of ASTP and CMS regulations addressing information blocking, HIT certification, baseline technical specifications for interoperability, prior authorization and public reporting. The Cures Act also directed ASTP to develop and implement a voluntary national "trusted exchange framework and common agreement" (TEFCA) intended to organize health information exchange at scale around a set of agency-approved nonprofit and for-profit "qualified health information network" (QHIN™) entities.
- Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule: Published in 2020, the Cures Act Final Rule is ONC (ASTP)'s foundational interpretation of the statute that made substantial upgrades to its Health IT Certification Program; adopted the US Core Data for Interoperability (USCDI) as the baseline iterative, FHIR-capable standard for health data exchange recognized by federal agencies (starting with USCDI Version 1); and defined information blocking in practice as well as eight "exceptions" to information blocking necessary for health system operations.
- Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule: Finalized by ASTP in January 2024, this rule updates the Health IT Certification program by raising the technical baseline to USCDI Version 3 and elevating other specifications; adding interoperability reporting metrics for HIT developers to adhere to; adding AI components to the certification requirements (disclosure for "predictive decision support interventions"); and introducing patient and population health application program interfaces (APIs).
- Information Blocking Enforcement Regulations: After defining information blocking and exceptions in detail under the Cures Act Final Rule, ASTP, CMS, and the HHS Office of Inspector General (OIG) finalized measures and associated procedures as deterrents to would-be violators in 2023 and 2024.

CMS

- CMS Interoperability Regulations: The CMS Patient Access and Interoperability Final Rule (March 2020) and CMS Interoperability and Prior Authorization Final Rule (January 2024) promote cross-system interoperability and secure data access for patients and providers. The agency has created a set of FHIR-capable API requirements (payer-to-payer, prior authorization, patient access, and provider access) to improve data exchange functionality and performance measurement across a wide range of "impacted

payers" under CMS authority, including Medicare Advantage plans, Medicare and Medicaid/CHIP managed care plans, and Medicaid/CHIP FFS.[13]

- CMS Waivers: Recognizing the value of such integrated interoperability, in 2021 CMS issued Medicaid and CHIP program guidance encouraging states to incorporate "data and analytic infrastructure"[14] necessary for addressing beneficiaries' non-medical drivers of health ("social determinants of health," or SDOH) into their Section 1115(a), Section 1915(c), and Section 1905(a) state plan authorities for funding. To date, 48 of the 50 states (plus D.C.) have at least one active section 1915(c) waiver, while a dozen states are working under 1115(a) waivers with SDOH data components approved since 2022.
- Provider Disincentives Rule: This applies CMS discretionary powers under the Medicare PI, MIPS, and ACO Shared Savings programs to reduce or deny reimbursement for violators.
- Medicare Promoting Interoperability (PI) Program: Medicare PI began as a component of CMS' larger meaningful use incentive umbrella in 2011 and has operated in its current form since 2018. Acute care and critical access hospitals are required to report metrics over set periods of time in the four categories of electronic prescribing, health information exchange, provider-to-patient exchange, and public health clinical data exchange (each of which has several sub-component measures) as a condition of Medicare participation; those which fail to meet the scoring thresholds face reimbursement penalties.
- Medicare Merit-Based Incentive Payment System (MIPS): MIPS is part of the Quality Payment Program (QPP) established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to replace the older sustainable growth rate (SGR) physician reimbursement caps with a value-based system. The two MIPS tracks (traditional MIPS and Advanced Alternative Payment Methods, or APMs) require performance reporting for 95% of enrolled clinicians using the same four categories as the hospital PI program. Like the hospital PI program, they drive provider connectivity to digital networks while reinforcing the expansion and integration of core HIE and emerging HDU capabilities across statewide and regional service areas.

CMMI

- Medicare/Medicaid Innovation Models and Accountable Care Mandates: These require comprehensive data sharing and reporting to support new payment and service delivery models focused on achieving equitable, affordable, person-centered care. The transition to value-based care creates demand for comprehensive, cross-sector data infrastructure to measure and analyze impact, outcomes, and cost savings. The Affordable Care Act established CMMI to be a focal point for more rapid and flexible value-based care experimentation. CMMI made interoperability a key component of its "whole person" accountable care models for participating providers and states. To date CMMI has run 90 different multi-year innovation models targeting specific geographies and patient populations as case studies for payment methodologies that incorporate quality and efficiency metrics—including, in many cases, interoperability requirements and HIE

[13] https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

[14] CMS. "SHO# 21-001: Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH). Available: https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf

partnerships. The Accountable Health Communities (2017-2022), Primary Care First (2021-present), and Making Care Primary (2021-present) models are especially noteworthy for the role of HDUs in achieving care coordination and integrating non-clinical information at scale.

CDC Public Health Modernization

- The CDC has emphasized expanding the capabilities of state and local public health jurisdictions by prioritizing investments in public health data, infrastructure modernization, and integrating clinical and public health data to improve population health and emergency preparedness. The imperative to continue supporting crosscutting HIE capabilities as integral public health infrastructure has been reflected in a substantial multi-year funding commitment through the CDC's Data Modernization Initiative (DMI) and associated $4.5 billion Public Health Infrastructure Grant (PHIG) distributions to over a hundred state and local PHAs.

Value-Based Care and Payment Models

- The shift towards value-based payment (VBP) from fee-for-service models across CMS and Medicaid is creating a demand for data interoperability and analytics to support quality measurement and reporting, which aligns with HDU capabilities. HDUs allow the sharing of information through secure, EHR-agnostic networks and provide a more complete picture of patients and population under risk contracts. This enables greater care coordination and identification of gaps in care, critical to success in value-based care agreements.

State Health Priorities

If past and present federal funding mechanisms, stakeholder incentives, and regulatory actions spanning well over a decade have paved the way for the HDU model, the work of actually building HDUs remains rooted in the states. Through laws, health department directives or various other forms of executive action, 41 states plus D.C. and Puerto Rico have designated a single statewide HIE. Another four states (NY, CA, PA, & TX) have formalized multi-level "federated" models that include several well-established regional HIEs operating under a larger network umbrella or statewide data sharing framework. Both types of HIE recognition are the natural foundation from which HDUs arise—less because of the formal use of "HDU" terminology, and more because public sanction and formal state partnership typically help facilitate the necessary scope of connectivity and engagement from stakeholders across the health ecosystem. In practice, many state-designated HIEs (and a few statewide HIEs without official recognition, though they still work closely with state and local PHAs) already operate as *de facto* HDUs without the title.

In 2022, Maryland enacted legislation officially recognizing its state-designated HIE, the Chesapeake Regional Health Information System (CRISP) as its HDU, making it the first and to date only state to do so (though similar bills have been introduced in other statehouses). The change in title was not a change in how CRISP operates so much as an acknowledgement of the effective capabilities and use-case connections that the organization has developed with public and private health actors across Maryland, consistent with reach of the HDU model beyond traditional HIE parameters. For CRISP, the most impactful parts of the law in question (HB 1127, MD Code Health-Gen 19-145) were actually its expansion of the state's provider connectivity mandate to cover prescription dispensers and the creation of a six-member

"consumer advisory council" to represent the interests of a broader segment of the public via concerned organizations. These provisions in Maryland and other states—both proposed and enacted—underscore how state actions strengthen emerging HDUs' positions in their health systems and make the HDU model a fact on the ground, including through the following mechanisms:

Connectivity Mandates

- Statutes that require health care providers, payers, and other stakeholders to connect to the state-designated HIE or HIE-mediated data exchange system (typically in phases, over a multi-year time horizon with rolling deadlines) are currently in force in ten states. Maryland, New York, Nebraska, Connecticut, and California mandate that most inpatient and outpatient facilities and electronic prescribers join their state HIEs/HIE networks or face legal penalties, while North Carolina achieves much of the same goal by making connection to the state HIE a provider condition of participation in Medicaid. Nevada, Arizona, Michigan, and Florida limit the data sharing requirement to Medicaid MCOs—and in Florida's case, "low-income pool" hospitals that receive a certain subset of Medicaid funds—however the proliferation of MCO enrollment in recent years (nearly three-quarters of beneficiaries nationwide by 2021) means that MCO connectivity still has great value as policy.

Data Stream Integration

- The most successful HIEs and emerging HDUs have typically achieved a position of primacy and centrality in their states' public-sector data networks, such that the vast majority of publicly-sanctioned health information transactions go through them (and as a consequence, the HDU plays a leading role in data standardization, provider technical assistance, non-clinical referral systems, and data sharing with federal partners, among other functions). This has been accomplished in many states by a combination of natural evolution and consolidation during the HITECH era and the COVID-19 pandemic; however, state laws and health department directives have also played a key role. The most integrated states have purposefully merged pre-existing health information exchanges with disease-specific clinical data registries (CDRs), immunization information systems (IIS), and all-payer claims databases (APCDs) to operate under a single entity. In a dozen cases, the entity is the state information technology office or a similar subset of the state health department; in the rest of the states, it is an independent or chartered nonprofit that manages the streams under contract.

Enumerated Use Cases and Governance

- The scope of state and regional HIE operations has grown well beyond "legacy" point-to-point transmission of patient records—yet many state statutes and regulations date from the legacy era of HIT adoption and so do not reflect the realities of current multi-functional HIE networks, much less the full potential of the HDU model. Working with their HIEs and other stakeholders (including Civitas), states are in the process of updating laws to explicitly acknowledge the many roles played by emerging HDUs and match expanded use cases with expanded accountability to public and community partners (which not only improves performance, but better positions them for federal funding opportunities and recognition). The revisions typically cover syndromic surveillance and disease registry integration with PHAs; chronic care management and value-based care initiatives (such as leadership in CMMI model implementation); data

standardization, especially regarding health-related social needs data; patient consent management responsibilities; and research partnerships with academic institutions. Alongside the use cases are provisions for larger and more representative HIE/HDU advisory bodies that are population focused (e.g. rural hospitals) or tailored to the oversight of specific high-value functions (e.g. artificial intelligence).

Sustainability Mechanisms

- HIEs have made meaningful strides toward greater financial self-sufficiency since the end of HITECH distributions in 2021. Nationwide, the median state HIE receives roughly 40% of its annual budget from MES allocations, while most of the rest comes from combinations of state support and participant fee schedules that vary from state to state. A handful of states have specifically authorized and funded HIE/HDU projects through their annual appropriations processes as health department initiatives, but this is still rare and only one state (Missouri) has adopted this approach at scale to supplement state Medicaid expenditures for the express purpose of developing HDU capabilities. State dollars used by HIEs often come from more general-purpose grant programs that the HIEs have pursued themselves, and recently states have more closely aligned such grants with data modernization. However, the most robust and consistent support mechanisms are those which authorize the collection of fees from exchange participants to generate revenue, or else create a dedicated tax with receipts earmarked for HIE investment. The former approach is now used by most HIEs, which adjust the fees that they charge based on participant type, size, location, or level of service utilization (e.g. large acute care hospitals vs rural community care hubs). The latter exists in its purest form in Vermont, which levies a 0.199% tax on all commercial health insurance claims in the state and deposits the proceeds into a “Health IT Fund” to support Vermont Information Technology Leaders, the state’s emerging HDU.

HDU Models

Given the variation in state needs and infrastructure, HDUs can be implemented through different models to meet local, regional, and state requirements and to meet baseline use cases. The five main HDU models include inherent cooperation with state health agencies and are described below:

Centralized HDU Model

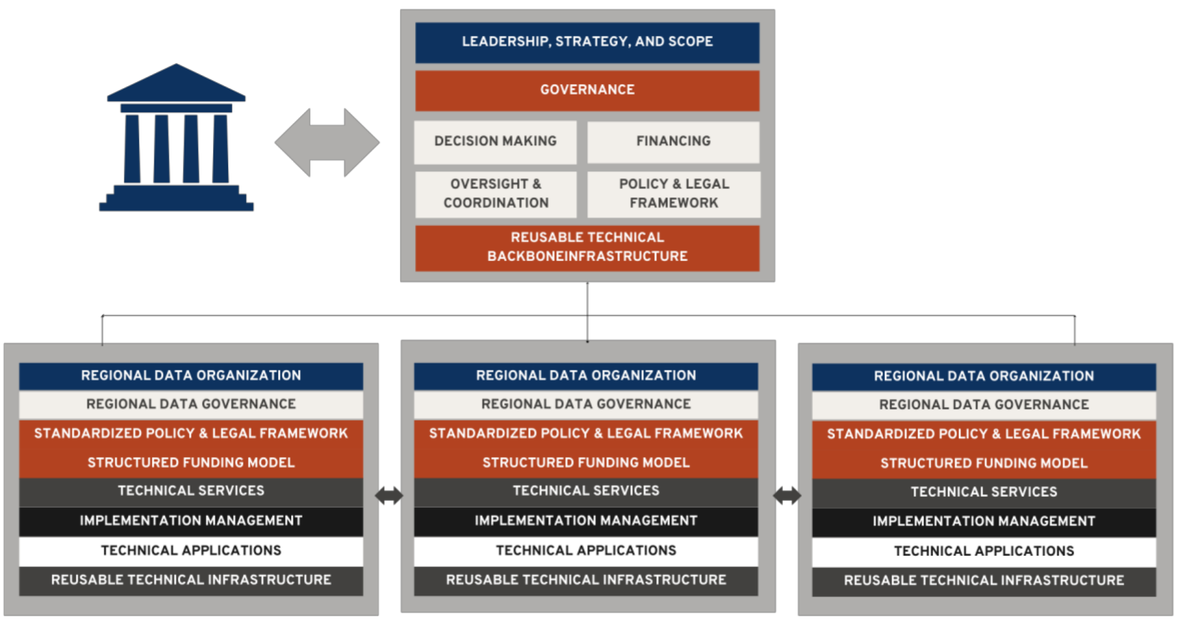
A single designated entity or agency with state cooperation designated to coordinate, operate, and provide technical services for health data management.

Bifurcated HDU Model

Separate entities manage governance and technical operations and collaborate to manage electronic health information technical services and ecosystem.

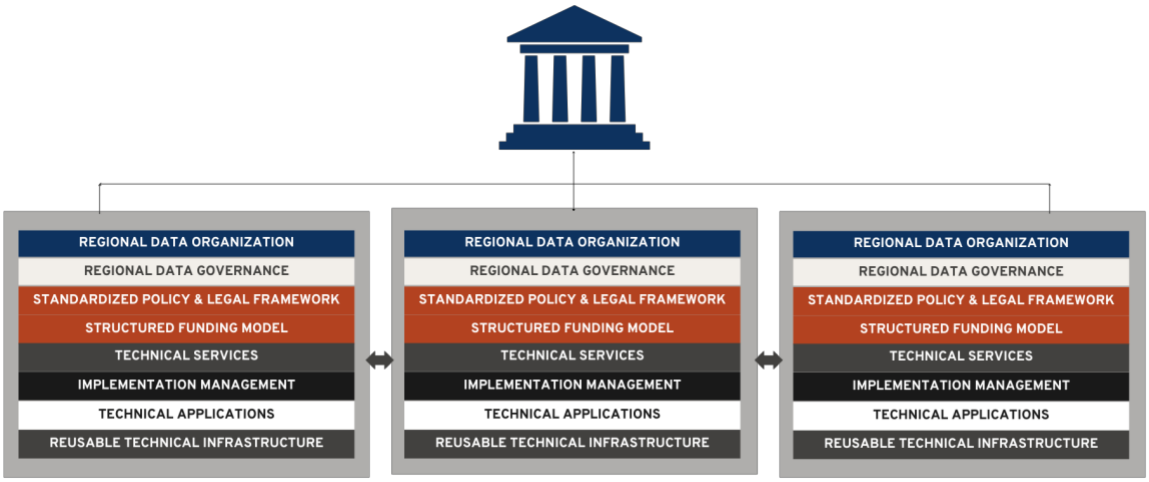
Coordinated HDU Network Model

In cooperation with the state, a coordinating entity coordinates and standardizes policy, procedures and the integration of multiple regional or sector-specific data networks. Vendor-based networks or a private network (e.g., medical society network) are not considered HDUs, but they may be connected to a public-private HDU as network partners aligning to and abide by the state data exchange policies.



Network of Networks Model

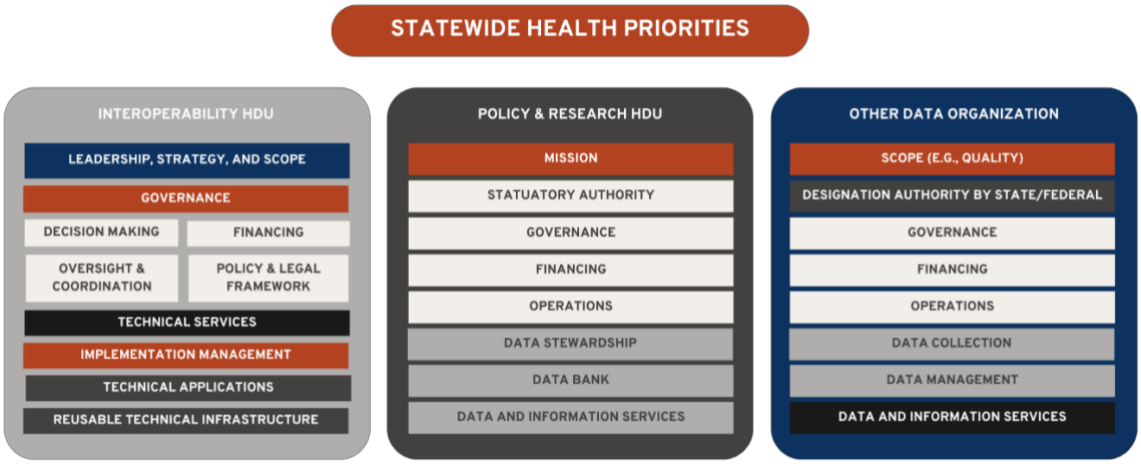
Multiple data entities participate in an aligned governance structure, facilitating comprehensive data exchange while retaining local autonomy without a central coordinating entity or centralized backbone of technical services. Challenges may persist if there is not a coordinating authority, as it may appear in direct competition with the other regional networks.



Integrated Health Data Network Model

An integrated ecosystem of health data resources aligned to common statewide health prioirities. Each data organization and network may have a different data stream from health partners (e.g., clinical data from hospitals, claims data from MCOs and payers etc.) with each serving a different purpose in the health ecosystem. Examples include but are not limited to:

- Clinical data from hospital emergency rooms to a primary care provider via the interoperability network of an HDU to notify the provider of an event for follow up.
- Claims data aggregated across all payers for health policy and cost containments analytics by the All Payers Claims Database (APCD).
- Reporting of quality data from clinical settings using EHR data and/or claims data for quality improvement measurement and practice transofrmation support through a Regional Health Improvement Collaborative (RHIC) or Quality Improvement Organization (QIO).



Case Studies and Future Directions

Future HDU initiatives will continue to focus on expanding the scope of health data integration to address critical health system needs. Upcoming case studies will explore the role of HDUs in the following areas:

- Quality Improvement: Demonstrating how HDUs drive quality improvement at the state level through enhanced data sharing and analytics.
- HRSN and Referral Networks: Outlining the role of HDUs in integrating HRSN data into clinical care and referral networks.
- Behavioral Health Data Exchange: Highlighting the importance of secure, privacy-compliant exchange of behavioral health data within HDU frameworks.
- Advancing Interoperability with FHIR: Showcasing HDU capabilities to support emerging data standards and use cases.
- Public Health Data Modernization: Exploring how HDU infrastructure supports public health data modernization and integration with health care systems.
- TEFCA Alignment: Defining how HDUs interact with the TEFCA framework, as well as national networks and frameworks to meet local and community health needs.
- Health AI Governance: Learning from deep expertise and lessons of health data exchange, states can be supported by HDU governance infrastructure to assist with inclusive multistakeholder health AI governance.

Next Steps and Call to Action

HDUs represent a critical advancement in state and region-level health data governance, offering a flexible and sustainable model for integrating clinical and non-clinical data. By adopting HDU frameworks, states and regions can build on existing HIE investments to create a comprehensive health data ecosystem that supports public health, care delivery, and community well-being. States should focus on strengthening their policies and legal frameworks, establishing sustainable financing models, and promoting stakeholder engagement to realize the full potential of HDUs in achieving their health data goals.

Civitas invites stakeholders and community partners to provide feedback on this resource. The period for public comments will close on January 31, 2025. After Civitas makes updates, we will publish the version and host a webinar to further discuss both how to use the framework and to hear from those who are implementing HDUs, expanding their model, and others interested in the potential of HDU in furthering specific use cases, such as public health data modernization or quality improvement. Civitas is committed to evolving our thinking about and understanding of HDU and wants to hear about other potential new use cases. We intend to publish a series of supportive case studies that further articulate the value of HDUs.

Additional Resources

The following list includes resources for additional reading on health data ecosystems.

- Consortium for State and Regional Interoperability (CSRI) – HDU Maturity Model
- New England Journal of Medicine – The Role of Health Data Utilities in Supporting AI
- American Journal of Public Health – Regulations and Funding to Create Enterprise Architecture for a Nationwide Health Data Ecosystem

- Manatt – State Health Data Organizations: A Framework
- Civitas Networks for Health – HDU Framework – A Guide to Implementation
- Civitas Networks for Health and Maryland Health Care Commission – Advancing Implementation of Health Data Utility Models