InterSystems
Creative data technology

InterSystems Response to

Request for Information

Department of Health and Human Services

Centers for Medicare & Medicaid Services (CMS)

Health Technology Ecosystem

[CMS-0042-NC]

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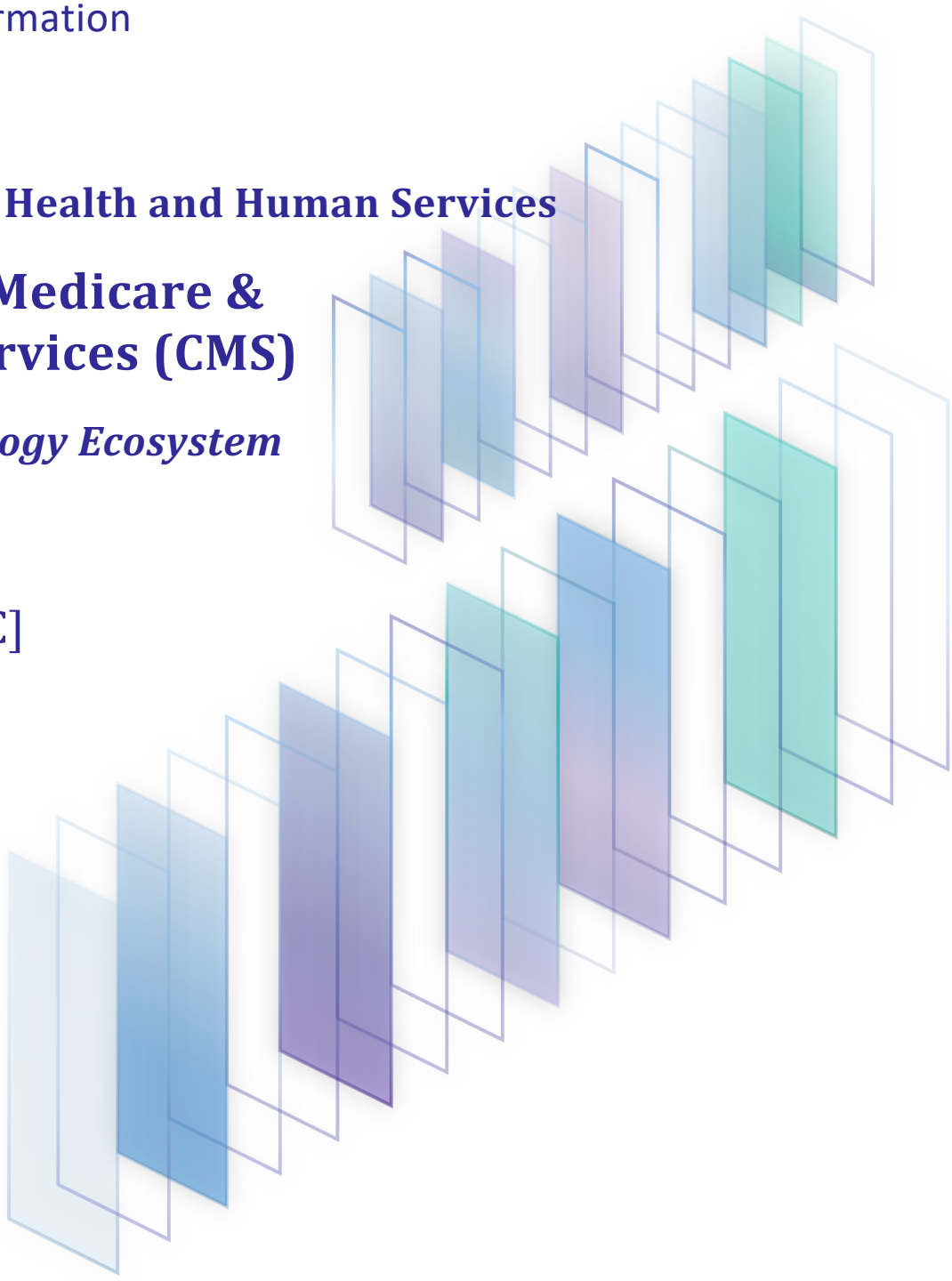

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Table of Contents

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Executive Summary

InterSystems appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS), Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) information, insights, and perspectives on the market of digital health products for Medicare beneficiaries as well as the state of data interoperability and the broader health technology infrastructure. As noted by CMS and ASTP/ONC in the Request for Information (RFI), despite the substantial progress in building a comprehensive digital ecosystem for health information, there remain gaps that hinder seamless and secure flow of health information between patients, providers, and payers and challenges to enabling digital workflows supported by modern tools.

About InterSystems

InterSystems Corporation is a global software company supporting customers in over 100 countries from its headquarters in Boston, Massachusetts and other offices throughout the world. Since it was founded in 1978, InterSystems has been a leading technology innovator in data management, interoperability, and analytics software that clients rely on to solve their most important strategic data problems. InterSystems software is used to manage the most important data in healthcare. Customers developing and running mission critical health data systems include:

- Government agencies such as the Department of Veterans Affairs, the Social Security Administration, the Indian Health Service, and the Department of Defense Military Health System
- Major healthcare providers, including the top 20 US hospitals and healthcare systems
- Leading software companies, including Epic, Sunquest, Netsmart, and QuadraMed
- Lab companies, including Quest Diagnostics, Roche Diagnostics, and NHS Labs
- Health information networks, including eHealth Exchange and 15 state HIEs covering more than 40 percent of the U.S. population
- Payer organizations, including UnitedHealthcare Optum, Aetna, CVS Caremark, Blue Cross Blue Shield Association, and several Blue Cross Blue Shield affiliates

InterSystems software is renowned for its high performance, data-centric architecture that seamlessly integrates sophisticated data storage, interoperability, and analytics. It excels in mission-critical environments, such as healthcare and finance, that require high-volume data management, scalable transaction processing, real-time interoperability, and complex analytics. With strong support for evolving industry standards and a commitment to continuous compatibility, InterSystems ensures reliable data exchange and long-term stability.

Centers of Medicare and Medicaid Services (CMS): Mission and Objectives

The U.S. health technology ecosystem is evolving rapidly, largely because of CMS leadership, in such areas as value-based payment, price transparency, interoperability, and patient empowerment. A common theme throughout this RFI is the appropriate role for CMS and ASTP/ONC in shaping the health IT ecosystem moving forward, and we urge continued leadership in standards definition

(FHIR APIs and TEFCA participation, for example), aligning incentives (value-based care, promoting Interoperability, etc.), and ensuring equity (Medicaid modernization and social determinants of health integration).

As one example, we have seen the impact that CMS and ASTP/ONC have had in fostering digital health innovation through their support of open and collaborative standards for interoperability. By ensuring that all products and network participants are playing by a common set of rules, CMS and ASTP/ONC have ensured there is critical mass to catalyze the growth of the digital health market and encourage new product entries.

In addition to its use of regulatory and policy levers, CMS, as the nation's most important healthcare payer, also has a generational opportunity to lead the healthcare industry to transformational breakthroughs. Using unified health data, CMS can elevate population health, ease provider burden, and maximize return on expenditure by harmonizing data from diverse sources, unifying clinical and claims information, streamlining provider data, and integrating artificial intelligence and machine learning (AI/ML) technologies.

Evolving to Unified Health Data

While current interoperability and health information exchange technologies are fundamental to data sharing, additional functionality is needed to enable the development and deployment of transformative health solutions. The opportunity to effect positive impact on the delivery and administration of care through technology requires the production of intuitive, flexible solutions that work together seamlessly and simplify the user experience. This in turn is predicated on the availability of unified health data.

Unified health data requires the consolidation of health information from multiple, disparate sources into standardized and interoperable longitudinal health records. Data needs to be integrated across medical records, claims, labs, imaging, pharmacy, and potentially wearable devices, telehealth, and non-health sources, before being standardized according to common health data models and standards. This enables clinicians, payers, researchers, and public health agencies to access and act on patient and population data to facilitate informed decision-making, care delivery, and centralized administration. Unified health data also needs to be secure and controlled by governance frameworks to enable data privacy and consent management, thus meeting regulatory requirements and protecting individual rights.

Unified health data necessitates a broader collection of technologies than those used for basic health information exchange:

- **Data harmonization** evolves beyond granting access to data from external sources, to transforming it into a consistent, standardized structure so it can be accurately integrated, compared, and analyzed. In practical terms, health data harmonization necessitates asserting patient identity, acquiring the corresponding medical records, normalizing and deduplicating the contents, and constructing a longitudinal medical record that incorporates all patient data.
- **Consolidated clinical viewers** present clinicians and other authorized personnel with a curated view of unified health data. An effective viewer will provide a longitudinal representation of all harmonized data for an individual patient, member, beneficiary, or

claimant, and will also identify the provenance of source data that has been assembled, normalized, and deduplicated from multiple constituent sources.

- **Connected personal health records** enable patients to take an active role in their healthcare, by providing them with convenient access to their health records and personalized education resources. They also enable providers, health systems, value-based care organizations, health plans, and software developers to create the digital front door needed to maximize patient engagement. They provide patients and their authorized caregivers with an array of tools to manage outreach, scheduling, and billing, and facilitate streamlined electronic communications, access to instructions and questionnaires, and unified alerts and notifications. Powered by unified health data, connected personal health records give patients a longitudinal view of their information from multiple facilities, eliminating the need to manually log into separate, tethered EMR solution portals.
- **Application and service development and integration** enables coordinated application services spanning internal and external applications and systems to be developed, managed, monitored, and adequately protected using tools like application development environments, API management, business process orchestration, and human workflow integration. In the context of unified health data, these technologies enable the development, integration, and coordination of disparate applications and services that operate seamlessly across internal and external systems and data sources.

Other advanced capabilities can be combined with unified health data for maximum effect. These include:

- **Provider data management** unlocks a range of advanced use cases that integrate patient data such as clinical, claims, and social determinants of health with accurate, enriched provider data (credentials, affiliations, specialties, performance) to improve care delivery, operations, and analytics. Practical examples include care delivery and coordination, clinical pathway optimization, and intervention planning based on provider performance.
- **Artificial intelligence and machine learning (AI/ML)**. While the promise of AI/ML is profound, it can only be effective when it is applied to current, accurate data. In this respect, unified health data becomes a force multiplier for real world AI/ML. Practical applications include detecting the hallmarks of medical conditions based on the information and trends in longitudinal medical records; easing provider burden by using AI/ML technologies to streamline the user experience; and reducing fraud, waste, and abuse by reconciling medical claims with their corresponding encounter records.

Unified Health Data at CMS

CMS has a unique opportunity to lead the healthcare industry by example while reaping the rewards of transforming its internal operations by driving technology innovation within the agency. By integrating clinical, claims, demographic, and provider data into a standardized, longitudinal data framework, CMS can strengthen program administration, enhance health equity, and drive better outcomes at scale. Potential applications of unified health data at CMS include:

- Reducing fraud, waste, and abuse by linking claims to clinical data. This will enable to agency to verify services rendered and detect fraud, waste, and abuse by reconciling clinical activity with billing.

- Improving payment accuracy by supporting risk-adjusted payments in Medicare Advantage, ACOs, and other value-based models.
- Providing population health and health equity insights by combining medical records, claims, and social determinants of health data to analyze and address disparities in access, care, and outcomes. This will allow the agency and its partners to target interventions and investments in underserved populations more effectively.
- Streamlined reporting and burden reduction by augmenting provider-submitted quality reports with quality metrics calculated from unified health data. This can enable real-time quality tracking and compliance monitoring across providers and states.
- Improved beneficiary engagement by allowing beneficiaries to access their complete health record, including claims, diagnoses, medications, and provider visits, across disparate health systems via their connected patient health record. This can also enable personalized plan recommendations and decision aids using a unified view of medical history.
- Integrating existing provider enrollment and provider data management workflows and implementing a national directory of healthcare providers and services that is interoperable with commercial provider directories via FHIR endpoints and standardized data models.
- Enhancing policy design and evaluation by identifying cost drivers, treatment variation, and health disparities more precisely by reconciling clinical services and payments across patient cohorts and populations and incorporating longitudinal, multi-source datasets to simulate policy changes involving coverage rules, risk scoring, and quality metrics.

Unified Health Data in Practice

The benefits of achieving unified health data are compelling, and real-world experience illustrates what CMS can achieve by embracing this approach. Some examples include:

Enhancing care coordination and reducing costs—Manifest MedEx, California's largest nonprofit health information network, is a designated Qualified Health Information Organization (QHIO) by the California Health and Human Services Center for Data Insights and Innovation. Supporting over 38 million patient records, Manifest MedEx uses InterSystems technology to integrate clinical and claims data from hundreds of hospitals, clinics, and health plans. This unified health data has led to improved care coordination, a reduction in duplicate testing, and enhanced public health reporting capabilities across the state.

Accelerating innovation in digital health—eHealth Exchange, the largest health information network in the United States, is accelerating digital health innovation at a national scale. As a designated Qualified Health Information Network™ (QHIN™) under the Trusted Exchange Framework and Common Agreement™ (TEFCA™), eHealth Exchange connects tens of thousands of healthcare organizations including 75% of U.S. hospitals, 60 regional and state HIEs, and five federal agencies through a single, scalable data-sharing hub, with more than two billion inbound transactions monthly.

To meet the demands of nationwide interoperability, eHealth Exchange uses a cloud-hosted, fully managed service operated by InterSystems to ensure high availability, performance, and security. The eHealth Exchange Hub underpins a variety of innovative public health data exchange applications including a FHIR-based adverse events monitoring application, an automated

electronic case reporting application, and a nationwide disaster preparedness and response application.

By implementing unified health data using the InterSystems platform, eHealth Exchange is not only reducing operational complexity and administrative burden but also enabling faster, more secure, and more intelligent data exchange across the healthcare ecosystem. This positions the network as a national leader in digital health transformation and public health innovation.

Value-Based Care—Healthfirst, a provider-sponsored health plan, has partnered with InterSystems to use real-time unified health data to improve performance on critical, time-sensitive HEDIS measures. More specifically, leveraging common standards and InterSystems technology to harmonize and normalize data from disparate sources, Healthfirst has automated three key processes: identifying qualifying quality events from parsed ADT feeds; generating daily reports that list impacted members and required follow-up care; and securely transmitting targeted alerts to the appropriate clinicians to enable prompt follow-up care.

This automation replaces previously manual workflows, allowing for faster, more efficient interventions. As a result, Healthfirst achieved significantly better performance in measurement year 2024 on several time-sensitive HEDIS measures:

- FUM (Follow-Up After Emergency Department Visit for Mental Illness): 34 percent better performance (from 44% to 59% – 15 percentage point difference).
- TRC (Transition of Care – Medication Reconciliation Post-Discharge): 34 percent better performance (from 40% to 53% – 13 percentage point difference).
- FUA (Follow-Up After Emergency Department Visit for Substance Use): 33 percent better performance (from 29% to 39% – 10 percentage point difference).

These results demonstrate how real-time data integration and intelligent automation can drive measurable improvements in quality performance and care coordination.

Conclusion

As the nation's most important healthcare payer, CMS is accelerating the evolution of American health and wellness through a bold digital health strategy that empowers patients, streamlines care coordination, and fuels seamless health data interoperability. Across the country, HIEs are demonstrating the power of connected data by delivering real-time insights that improve patient outcomes, strengthen public health and emergency response, and accelerate progress in value-based care and quality reporting.

Looking forward, CMS has a generational opportunity to lead the healthcare industry to transformational breakthroughs in patient care. By harnessing the full potential of unified health data, CMS can elevate population health, ease provider burden, and maximize return on expenditure. Through harmonizing data from diverse sources, unifying clinical and claims information, streamlining provider data, and integrating AI/ML technologies, CMS can unlock the true power of data-driven healthcare—and set a bold example for the entire U.S. health IT ecosystem.

For a demonstration of unified health data, visit:

https://www.intersystems.com/cms/unifiedhealthdatademo

Requested Use Case Feedback

B. Patients and Caregivers

As a technology vendor, InterSystems is providing responses to selected items in this section based on customer experiences.

1. Patient Needs

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

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

b. If you had a personal assistant to support your health needs, what are the top things you would ask them to help with? In your response, please consider tasks that could be supported or facilitated by software solutions in the future.

Based on engagement with a broad range of health ecosystem participants—providers, payers, pharmacies, hospitals and health systems, HIEs, and national networks—InterSystems believes that patients want a robust digital platform that empowers patients and their caregivers.

Such a platform provides on-demand access to medical records, enabling them to stay informed and engaged in their care decisions. It also provides caregiver proxy access, enabling them to manage the health needs for children, elderly parents, and other loved ones. The platform unifies and integrates data from multiple systems, making it easier to coordinate care across providers, especially for chronic or complex conditions.

Patients have an increasing desire, if not expectation, that the platform include features like online appointment scheduling, secure messaging, and billing tools to streamline interactions between patients and healthcare providers, making them more efficient and effective. The platform supports personalized education resources, helping users understand conditions and treatments in a tailored manner, and of course, this information is presented in the user's preferred language and available on mobile and other platforms.

A digital personal assistant for health can assist with most, if not all, of these tasks on behalf of a patient, and a modern health IT platform is expected to provide patients' digital assistant of choice reasonable access to perform these tasks.

PC-3. Are you aware of health management, care navigation, or personal health record apps that would be useful to Medicare beneficiaries and their caregivers?

InterSystems Personal Community, a source-neutral API-based digital front door platform, is an example of how these and similar services can and are being provided today. Personal Community can be tethered to an electronic health record (EHR) or claims system to serve as a white-labeled portal. It can be used as a digital front door development platform

supported by an extensible data model, and it can be deployed over an HIE or other aggregate record to deliver a comprehensive view of a beneficiary's full health record.

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?

With EHR adoption and information networks such as HIEs and QHINs, there are plenty of data sources for real-world data (RWD) or real-world evidence (RWE) development. A robust clinical data interoperability technology is needed to manage data exchanges and aggregation networks. With approved data usage, the information, filtered by the intended use, can flow automatically to a registry or federated network of registries. The technology platform can perform further harmonization, data quality check and improvement, and phenotyping if required, to support analytics. Achieving this data flow inherently requires appropriate data coding and capture at the source, so that data can be correctly transmitted and presented in the HIE or other QHIN-connected health data source.

Such flexible use case driven registry networks can achieve the scalability and performance needed for CMS analysis. Federated network analytics is increasingly used by many organizations and governments around the world, which ensures agility.

2. Data Access and Integration

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?
b. What suggestions do you have to improve the Blue Button 2.0 API experience?
c. Is there non-CMS data that should be included in the API?

Blue Button is a great patient mediated data sharing service to facilitate care coordination and participate in important research efforts. To further enhance the value of Blue Button, future versions should incorporate the ability for patients to specify the type of data, sources, targets, and recipients as preferences, so only data expressly permitted by the patient is shared. Likewise, clinical data, such as problem list from EHR and medication list, are critical to support secondary use of the data such as real-world evidence development and clinical trial recruitment. Finally, it is logical to consider adding consent policies and clinical data pulls to Blue Button.

PC-10. How is the Trusted Exchange Framework and Common Agreement™ (TEFCA™) currently helping to advance patient access to health information in the real world?

a. Please provide specific examples.
b. What changes would you suggest?
c. What use cases could have a significant impact if implemented through TEFCA?
d. What standards are you aware of that are currently working well to advance access and existing exchange purposes?
e. What standards are you aware of that are not currently in wide use, but could improve data access and integration?
f. Are there redundant standards, protocols, or channels that should be consolidated?
g. Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information?

TEFCA is an important step in the evolution of the health IT ecosystem to providing true nationwide access for all patients to their health data, without regard to location or network. As health information exchanges (HIEs) were able to bridge divides and connect data between different EHR systems and private HIEs within states and regions, TEFCA can link those HIEs nationwide. The ecosystem can realize tremendous benefits as TEFCA continues to mature and various purposes of use become more clearly defined and implemented, whether voluntarily or mandatorily.

TEFCA and the QHINs are additive to, rather than a replacement of, the state and regional HIEs. As noted in PC-11, these HIEs provide significant services and benefits that are not duplicative of the national record exchange that is facilitated via TEFCA.

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

The majority of HIEs do not currently support direct patient access to their health information. However, by facilitating the exchange and consolidation of patient data from multiple EHRs and other data sources, HIEs help advance patient access to their health information. Without HIEs, information available to patients would be even more fragmented and siloed, including information that patients may access via a provider's patient portal. In this way, HIEs are critical to the health IT ecosystem and advancing patient access to health information in the real world.

HIEs are playing a transformative role in improving patient health data by enabling real-time, interoperable sharing of clinical information across disparate healthcare systems. In practice, this means patients benefit from the following:

- Reduced duplicative testing and imaging
- Fewer hospital readmissions, especially within 30 days
- Improved medication reconciliation and care coordination
- Faster, more informed clinical decisions, especially in emergency settings

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

The data shared through HIEs is increasingly valuable and timely, especially when integrated with health data utilities (HDUs) and social data. That stated, data completeness and standardization remain opportunities for improvement. While many HIEs provide

accurate clinical summaries, variability in data quality across providers and EHR systems can affect reliability.

b. What changes would you suggest?

To improve HIE effectiveness:

- Standardize data formats and terminologies across systems
- Promote the adoption of robust patient access portals within HIEs
- Enhance data governance and consent management to build trust
- Incentivize participation from smaller or rural providers

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

There are several high-performing HIEs that are providing a range of innovative services, including these five:

Healthconnect Texas (formerly Greater Houston Healthconnect)—Healthconnect Texas is one of the largest HIEs in the U.S., serving over 23 million Texans. It connects hospitals, clinics, and providers across the state, enabling real-time, secure data exchange. It supports emergency care coordination through programs like ETHAN, which diverts non-emergency 911 calls to clinics, reducing ER strain. Healthconnect Texas is a model for statewide interoperability, integrating with Medicaid and public health systems.

Healthix—Healthix is another large public HIE, covering over 20 million patients and more than 8,000 healthcare facilities in New York. It provides real-time alerts, longitudinal patient records, and population health analytics. Healthix is powered by InterSystems HealthShare, enabling robust data integration and TEFCA readiness. Healthix recently launched a partnership with CLEAR to provide patients direct access to their health records via a web portal. It also is a leader in public health reporting and COVID-19 response coordination.

East Tennessee Health Information Network (ETHIN)—ETHIN is a regional HIE that connects providers across East Tennessee. It focuses on care transitions, hospital readmission reduction, and behavioral health integration. ETHIN has been recognized for its community-based approach and its ability to support rural and underserved populations through efficient data sharing and care coordination.

Manifest MedEx—Manifest MedEx is California's largest nonprofit HIE, serving over 30 million patients. It combines clinical and claims data to support value-based care, public health, and health equity initiatives. It is a key partner in California's Data Exchange Framework and supports real-time admission, discharge, and transfer (ADT) alerts, risk stratification, and population health management.

CyncHealth—CyncHealth is a regional HIE serving Nebraska, Iowa, and surrounding states. It integrates clinical, behavioral, and social determinants of health (SDOH) data. CyncHealth is a national leader in HDU models and supports public health surveillance, opioid monitoring, and whole-person care.

These HIEs exemplify how regional and statewide exchanges can drive interoperability, care coordination, and health equity.

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

HIEs continue to play a vital role in the evolving health data ecosystem, even as national frameworks like TEFCA, vendor-led networks, private exchanges, and eHealth Exchange expand. While these broader networks focus on enabling nationwide interoperability, HIEs often serve as regional data hubs that deliver localized insights, public health reporting, and community-level care coordination. Many are contracted to support Medicaid and other state health programs. Their deep integration with local providers, public health agencies, and social services enables HIEs to address population-specific needs and support whole-person care in ways that national networks may not be equipped to handle alone. As such, HIEs complement national efforts by ensuring that data exchange is both broad and deeply rooted in local context.

InterSystems HealthShare supports HIEs by providing enterprise master person index (EMPI) and unified health record technology, aggregating data from multiple sources into a longitudinal patient view. It enables real-time data exchange, analytics, and care coordination. HealthShare also supports TEFCA participation and integrates with national and regional networks. InterSystems provides the technical platform for both eHealth Exchange (with two billion inbound transactions per month) and MedAllies, two of the first QHINs under TEFCA.

InterSystems IRIS for Health complements this by offering a high-performance data platform for building and scaling health applications, including those built on HIE data. It supports FHIR, SMART on FHIR, HL7, and other standards, enabling developers to create interoperable solutions that enhance HIE capabilities.

Together, these tools empower HIEs to deliver accurate, timely, and actionable data, advancing patient access and care quality across the healthcare ecosystem.

3. Information Blocking and Digital Identity

PC-14. Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 credentialing service providers (CSP)):

Widespread implementation of high-trust, high-security digital identity credential solutions (IAL2/AAL2 CSPs that are complaint with NIST 800-63-3 or similar standards) will have significant benefits and accelerate the adoption of digital health tools. Reliable and trusted digital identity creates a shared confidence within the ecosystem. It provides patients with greater assurance that despite a proliferation of apps and health data systems holding their data, their health information can only be accessed by them or those to whom they give permission. Conversely, it gives data holders an assurance when they are exposing data that the recipient is the appropriate party. Such confidence is essential for the ecosystem to function as envisioned.

However, the implementation of these tools will present challenges as well. It should also be noted that while a digital identity credential greatly assists with the identity resolution of users, it does not replace the need for a robust EMPI tool to handle record matching across systems.

For additional information on this topic, see the response to TD-3.

a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?

Sign up for some CSPs can be a labor-intensive process that requires patients or caregivers to have access to their personal identity documents and the ability to digitize them for submission. Some services require additional forms and in-person or video call visits to confirm identity. Additionally, these services may not be provided for minors, or minors may not possess the necessary documents to meet their standards. For reference, only 50% of U.S. citizens have a valid passport, which has similar requirements. One might assume that a similar threshold for accessing healthcare data may meet significant resistance and limited adoption. Several years ago, Japan introduced a standardized "My Number" card for accessing healthcare services, but widespread adoption is elusive. It can reasonably be presumed that in the U.S., already at-risk populations that use the healthcare system more frequently and have more complex medical needs such as children, the elderly, those with disabilities, and similarly situated individuals, are the least likely to enroll in these programs. Therefore, it is critical that all persons retain reasonable alternative methods for data access. Also note that there is significant evidence that healthcare consumers distrust private technology companies, which may further complicate adoption.

b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used?

If these credentials were more widely used, patients would be able to have a universal log in for all their health records, leading to less time spent preparing for appointments and improved quality of care.

c. What are the potential downsides?

Overreliance on a single login credential that grants access to all health records for a patient increases the risk of widespread data exposure in the event of a breach. To strengthen privacy protections and build public trust, policies should support giving patients meaningful, practical control over which types of health data are shared and with whom—enabling more secure, selective data exchange.

d. How would encouraging the use of CSPs improve access to health information?

CSPs would improve access to health data by providing one method of access for all records of a patient. However, this still requires appropriate identity data resolution on the backend to ensure that credentials for one person do not unlock records for a different person with the same or similar name, birthdate, or other demographic data, particularly when data is being shared between two different health data systems.

e. What role should CMS/payers, providers, and app developers have in driving adoption?

CMS can encourage or incentivize some form of patient access to CSPs for a large proportion of the healthcare-seeking population via Medicare and Medicare Advantage plans, as well as through state Medicaid programs. This can be phased in over time as part of CMMI model participation or included in Medicaid Advantage plan star rating criteria. Providers also have a clear benefit in recommending and evangelizing this solution to patients to ensure all relevant clinical information is available to them at the point of care. App developers are responsible for modalities to support CSP-based access within existing health apps that might contain relevant data.

CMS and ASTP/ONC are also in a position, particularly in coordination with other standard setting organizations, to set criteria for CSP solution participation in the health IT ecosystem. This criteria should be neutral, transparent, and objective.

f. How can CMS encourage patients to get digital identity credentials?

CMS can encourage participation through public awareness campaigns and by negotiating for lower cost methods of accessing these programs. For example, CMS can partially cover or reimburse enrollment fees for eligible patients.

C. Providers

As a technology vendor, InterSystems is providing responses to selected items in this section based on provider customer experiences.

1. Digital Health Apps

PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)? Please address all of the following:

While it is ideal to make all EHR data accessible for exchange in any format, that it is likely not practical to implement, nor does the benefit outweigh the burden; therefore, it is important to prioritize with a focus on real-world benefits. Clinical data that will make a difference in patient care is the most important. Operational data is useful for optimization and cost reduction can justify investment. Other types of data, like revenue cycle data, must be used within the organization and shared only when required.

a. Current challenges in accessing different data formats.

EHR systems usually have a mix of structured data (medications, allergies), semi-structured formats (lab results in PDFs, Patient Documents), and unstructured content (faxes, free text). Challenges in accessing this data include the following:

- Scanned documents and faxes lack machine readable structure, making them difficult to search, extract, or standardize (although new tools are helping to transform fax to text to structure).
- Free-text notes often contain rich clinical detail that require natural language processing (NLP) to be actionable.

- Structured data fields are easier to exchange but often inconsistently populated across EHR systems.
- The heterogeneity of data formats creates friction in workflows, impedes real-time decision-making, and adds burden to integration teams.

b. Impact on patient care quality.

The quality of patient care is negatively impacted when data cannot be easily accessed or exchanged. For instance, rural providers may lack critical history, leading to duplicate testing, delayed diagnoses, or unsafe prescribing; clinicians may miss key insights hidden in scanned images or free-text notes, particularly during transitions of care; and in emergencies, inaccessible formats slow care and increase risk. That said, not all data needs to be exchanged at the same priority; clinical data should guide decisions. For example, allergy, medications, and recent lab results are more actionable in real time than historical scanned documents.

c. Technical barriers to full data accessibility.

Full accessibility faces several technical challenges, including the following:

- NLP technologies still have limitations in extracting reliable data from scanned or handwritten records, despite recent improvements, but they are working well with audio data.
- Data normalization across systems is difficult due to varying clinical vocabularies, record structures, and local practices, but applications like integration engines that provide tools for data quality assurance and data transformations to modern standards like FHIR can help.

d. Cost or privacy implications of making all data formats interoperable.

Making all data interoperable increases integration and infrastructure costs, particularly for smaller rural systems, but cloud and pay-by-volume message solutions are key to reduce these costs.

e. Priority level compared to other interoperability needs.

This is a medium priority need, but not the most urgent. The highest priority remains the enabling of real-time exchange of structured data (preferably via FHIR APIs), which is likely to provide the highest return on investment for care coordination and safety. Enriching structured data with generative AI or NLP extracted information from free text and semi-structured sources is a higher priority.

2. Data Exchange

PR-5. Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each,

describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:

InterSystems technology is used extensively throughout the health data ecosystem, including several provider solutions. Support for FHIR APIs is integral to all InterSystems health solutions.

a. Patient Access API

InterSystems technology supports the Patient Access API that adheres to USCDI V6, CARIN BB 2.0. This technology is being updated to PDex 2.1 support.

b. Standardized API for Patient and Population Services

InterSystems FHIR repository of patient longitudinal health records allows querying all patient information using FHIR API for US Core. Adopting bulk FHIR retrieval of patient cohort information is on the development roadmap.

c. Provider Directory API

InterSystems Provider Directory supports the Da Vinci Plan-Net 1.1 IG. This solution allows querying the Provider Directory.

d. Provider Access API

InterSystems supports the Provider Access API that complies with CMS-0057 regulations. The current functionality supports individual FHIR queries, and it is on the development roadmap to adopt Bulk FHIR to pull data from the platform's FHIR repository. This API adheres to USCDI V6, CARIN BB 2.0 standards. InterSystems is in the process of updating our PDex IG support from 1.0 to 2.1. It is on the product roadmap to pair this API with an FHIR Attribution List service and Consent Service to control access to member records for the Provider Access API. The InterSystems solution also allows for consent to be applied to specific data types in the FHIR repository.

e. Payer-to-Payer API

InterSystems technology supports the Payer to Payer API that complies with CMS-0057 regulations. The current functionality supports individual FHIR queries, it is on the roadmap to adopt Bulk FHIR to pull data from our FHIR repository and receive Bulk FHIR payloads into the FHIR repository and longitudinal health record. This API adheres to USCDI V6, CARIN BB 2.0 standards. InterSystems is in the process of updating its PDex IG support from 1.0 to 2.1. It is on the product roadmap to pair this API a Consent Service to control access to member records for the Provider Access API. The InterSystems solution also allows for consent to be applied to specific data types in the FHIR repository.

f. Prior Authorization API

InterSystems will release its ePrior Authorization solution in June 2025. The ePrior Authorization solution complies with Da Vinci CRD 2.01, DTR 2.01 and PAT 2.01 IGs. InterSystems will update its solution to CRD 2.1, DTR 2.1, and PAS 2.1 later this year. The PAS solution supports polled subscriptions and on-demand notification to subscribed provider organization EHRs.

g. Bulk FHIR – Do you support Group ID-based access filtering for population-specific queries?

InterSystems is updating its FHIR Server to use the Bulk FHIR 2.0 standard this year for Bulk FHIR coordination. The current FHIR repository allows querying the Group ID assigned to patients. It is on the product roadmap to support bulk member match and Bulk FHIR for the retrieval of member information by provider groups.

h. SMART on FHIR – Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?

Yes, the InterSystems platform supports both EHR-launched and standalone app access. The InterSystems platform acts as a FHIR repository and the server that can be accessed by third-party applications using OAuth with assigned scope privileges.

i. CDS Hooks (for clinical decision support integrations)

The InterSystems platform has an action engine component that allows CDS Hook cards and rules to be built on the InterSystems IRIS for Health integration engine that can be integrated with clinical decision-support applications.

For example, in the ePrior Authorization solution, the CRD (Coverage Requirements Discovery) component acts as a CDS Hooks Server to handle CDS Hook payloads during the coverage requirements discovery process.

PR-8. What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?

a. What would be the benefits and downsides of using Bulk FHIR data exports from EHRs to CMS to simplify clinical quality data submissions? Can CMS reduce the burden on providers by performing quality metrics calculations leveraging Bulk FHIR data exports?

Bulk FHIR data export from EHR is a potentially useful methods for clinical quality data calculation and submission of providers. Market leading EHR vendors have already developed bulk FHIR export support but still require improvements such as cohort definition and export speed performance. In addition, importing bulk FHIR into a FHIR or OMOP repository for immediate quality measure calculation will be necessary to provide immediate feedback to the provider or allow verification. Chart review is commonly required for hybrid measures. A FHIR or OMOP repository can assist automated annotation using AI or manual verification. Such an approach will reduce the burden on the provider to build the analytics environment for reporting.

b. In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed?

Using the bulk FHIR and a FHIR or OMOP repository with analytics add-ons will achieve both interoperability and quality reporting on the same platform. For instance, InterSystems FHIR capabilities can ensure high performance and flexibility with bulk FHIR, FHIR repository, FHIR SQL projection, FHIR to OMOP, and vectorized data for AI based annotation.

c. Are there requirements CMS should consider for data registries to support digital quality measurement in a more efficient manner? Are there requirements CMS should consider for data registries that would support access to real-time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?

Current data registries are not using a common data model such as OMOP or using standard methods such as FHIR to ingest data. CMS can require that data registries use FHIR or OMOP if the registry data can be used for quality reporting. CMS can focus on a single set of technical standards for all registries. More importantly, while registries have the potential to support observational evidence that can reduce bias, a network of registries using the common data model can support federated analytics to compile a larger cohort of patients with similar conditions. In that way, the clinician can use the same registry for clinical care and accelerate diagnosis and select the optimal treatment with the best outcome.

D. Payers

As a technology vendor, InterSystems is providing responses to selected items in this section based on payer customer experiences.

PA-4. What would be the value to payers of a nationwide provider directory that included FHIR endpoints and used digital identity credentials?

Establishing a nationwide provider directory that includes FHIR endpoints can provide significant value to the payer community. (See response to TD-5 for more details.)

Currently, the burden of establishing and maintaining an accurate directory of FHIR endpoints lies with each payer and their data systems; the lack of accurate FHIR endpoint data can result in failed automated transactions and increased administrative overhead costs. For instance, the automation of the prior authorization process depends on both payers and providers being able to reach not only the appropriate entity, but also that entity's correct FHIR endpoint to support each step of the process; when a data transaction is directed to the wrong data endpoint, the automated transaction fails and manual intervention is required—a reversion back to the current cumbersome process. A nationwide provider directory with FHIR endpoints can significantly reduce these and similar challenges and support an expansion of process automations, thereby reducing costs and burdens for payers.

The value of the nationwide directory for payers (and others) can be further enhanced if the directory also supports interoperability with commercial provider directories and includes provider data management functionality.

The integrity and security of the data in the nationwide directory is paramount. It also is desirable to allow providers to have direct access to the directory to update their data. With these two goals in mind, it may be beneficial to require digital identity credentials to allow a provider to "self-service" their profile on such a provider directory to ensure accuracy of certain fields like languages spoken, open hours, office phone number, etc. This provides some degree of control over the directory while also allowing for more up to date information to be added in near real time directly from the source.

Conversely, InterSystems presumes that a public version of the directory will be open and accessible to the public via the internet. Patients and caregivers can use this public version to research providers in their area. This should not require credentials to log in for access. Indeed, few hospitals "Find a Doc" sites require this today.

E. Technology Vendors, Data Providers, and Networks

1. Ecosystem

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?

The following is a roadmap how CMS can stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers.

Short-Term Steps (Next 2 Years):

Expand Access to Standardized APIs: Continue CMS prioritization of FHIR-based APIs to enable developers to access Medicare data securely and consistently.

Promote Digital Identity and Access Tools: Public confidence and comfort in accessing sensitive health data, as well as the current legal and regulatory requirements for data privacy and security, make user identity resolution an essential element for expanded adoption of digital health services. However, these solutions must be easy to adopt, ubiquitous in application, and minimize the transactional burden on users. CMS should continue to explore the adoption of secure digital identity solutions (Clear, Login.gov, ID.me) to simplify patient access. To promote widespread adoption and implementation of these solutions, CMS should consider what standards are required to ensure efficient interoperability within the ecosystem, so that technology providers like InterSystems can integrate these identity frameworks to ensure secure, authenticated access to patient data.

Support Developer Sandboxes and Test Environments: CMS can offer sandbox environments with synthetic Medicare data that can simulate real-world data exchanges and thereby accelerate prototypes and testing.

Launch Innovation Challenges and Grants: CMS can fund pilot programs or competitions focused on caregiver tools, chronic disease management, and care navigation.

Longer-Term Steps (3+ Years):

Incentivize Integration with National Networks (TEFCA, eHealth Exchange): CMS can require or reward integration with national frameworks.

Measure and Certify App Impact: CMS can establish a certification program for digital tools that demonstrate improved outcomes or reduced costs.

Expand Data Types Available to Developers: Beyond claims and clinical data, CMS can release SDOH and behavioral health data.

To advance these measures, CMS and ASTP/ONC can collaborate with trusted industry partners who have existing and established capabilities in these areas, enabling faster piloting and implementation. For instance:

- *InterSystems IRIS for Health* supports FHIR and other standards, allowing developers to build apps that integrate with Medicare data ecosystems quickly.
- InterSystems provides developer-friendly environments and APIs that simulate real-world data exchange, accelerating prototyping and testing.
- InterSystems platforms can serve as the data backbone for these pilots, enabling rapid deployment and evaluation.
- *InterSystems HealthShare* is TEFCA-ready and supports bidirectional data exchange.
- InterSystems can support real-world data analytics to evaluate app performance and outcomes.
- InterSystems platforms already support multi-source data aggregation, including SDOH, enabling more holistic app development and expansion to new types of data.

By leveraging a robust, standards-based platform with readily available functionality, CMS can create a developer-friendly ecosystem that accelerates innovation while ensuring data security.

TD-2. Regarding CMS Data, to stimulate developer interest--

InterSystems appreciates CMS efforts to modernize its data ecosystem and catalyze innovation. The recommendations listed in the following items reflect the needs of developers building scalable tools that serve patients, providers, and payers.

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

Real-Time Claims and Prior Authorization Data—Access to real-time or near real-time claims status, prior authorization requests, and outcomes via standardized APIs allow developers to build tools that reduce administrative friction, alert providers to documentation gaps, and support faster care delivery.

Provider Network APIs with Appointment Availability—While provider directories exist, APIs that expose real-time availability and scheduling capabilities (integrated with MA and Medicaid plans) enhance digital front-door solutions and care navigation tools.

SDOH Linked to Beneficiaries—Access to de-identified, ZIP code-level SDOH indicators (transportation barriers, housing insecurity) tied to CMS beneficiaries enables developers to embed equity insights into clinical decision support and community resource referral platforms.

Expanded Medicare Advantage Encounter Data—Robust, API-accessible MA encounter and supplemental benefit data enable vendors to support risk adjustment models, identify care gaps, and personalize digital care plans more effectively.

Utilization and Cost Transparency Data—APIs providing plan-specific cost-sharing, utilization trends, and out-of-pocket estimators—aligned with the Transparency in Coverage rule—enhance patient engagement and informed decision-making.

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

Medicaid Data (T-MSIS)—Integration of Medicaid encounter data allows developers to build longitudinal patient records for dual-eligible beneficiaries, addressing a critical blind spot in care coordination and population health tools.

USCDI-Based Clinical Data from EHRs and TEFCA Networks—Combining clinical data with claims via TEFCA or QHIN-connected sources allow tools to deliver more comprehensive insights for providers and patients, supporting both care planning and analytics.

HIE Aggregates and Public Health Registries—Regional HIE data including labs, imaging, and ADT feeds, can complement CMS claims data to power real-time surveillance, care transitions, and population health reporting modules.

Environmental and Community Health Data—Public datasets from CDC PLACES, EPA, and similar sources provide context that enable tools to identify environmental and social risk factors affecting patient outcomes.

c. What obstacles prevent accessing these data sources today?

Siloed and Fragmented Data Infrastructure—Many valuable datasets (T-MSIS, Medicaid waiver data, for example) are not exposed through accessible, developer-friendly APIs, making integration labor-intensive and inconsistent across states.

Latency and Batch-Oriented Updates—CMS datasets often rely on quarterly or monthly updates, which limits the feasibility of real-time clinical decision support and dynamic patient engagement tools.

Lack of Centralized Consent and Identity Management—Without a unified, patient-directed authorization model across CMS and Medicaid systems, integrating multiple data types for a single individual remains complex.

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

Expose provider scheduling slots via public APIs—Public APIs that expose open provider slots enabling vendor apps to query for access. This promotes greater interoperability, more efficient patient access, and improved integration of patient scheduling into digital health platforms. While the specific API standardization and requirements vary, the overall goal is to make provider availability data readily accessible to various applications and systems.

eCQM and Quality Reporting APIs—APIs that allow vendors to automate clinical quality measure reporting reduce burden and enable smarter, EHR-integrated performance improvement solutions.

Behavioral Health Access APIs—APIs that expose behavioral health provider availability, treatment capacity, and plan coverage enable closing access gaps in this high-need area.

Real-Time Formulary and Pricing APIs—Expanding availability of real-time benefit tools and pricing transparency APIs for both Medicare and Medicaid populations enable cost-comparison tools and drive adherence.

TEFCA-Connected Nationwide Query APIs—CMS should support policies that encourage patient- and provider-directed access to TEFCA-connected data networks through third-party apps, enabling broader interoperability and innovation.

2. Digital Identity

TD-3. Regarding digital identity implementation:

As noted in the response to PC-14, widespread implementation of high-trust, high-security digital identity credentials (IAL2/AAL2 CSP which are complaint with NIST 800-63-3 or similar standards) provides significant benefits and accelerates the adoption of digital health tools. Reliable and trusted digital identity creates a shared confidence within the ecosystem. It provides patients with greater assurance that despite a proliferation of apps and health data systems holding their data, their health information can only be accessed by them or those to whom they give permission. Conversely, it gives data holders an assurance when they are exposing data that the recipient is the appropriate party. Such confidence is essential for the ecosystem to function as envisioned.

However, the implementation of these tools will present challenges as well. Also note that while a digital identity credential greatly assists with the identity resolution of users, it does not replace the need for a robust EMPI tool to handle record matching across systems.

For additional information on this topic, see the response to PC-14.

a. What are the challenges and benefits?

The benefits are simpler care coordination for the most medically complex and vulnerable members of society and their caregivers. It improves quality of care, adherence to care plans, and ignites value-based care models.

The challenges include creating a standard for which credentials are accepted and what kinds of information are required to use them. As noted in our response to PC-14, many digital identity solutions rely on government-issued photo identifications (such as drivers licenses or passports), which may not be held by all patients, particularly minors or certain low-income or otherwise vulnerable populations. An additional challenge is converting existing systems to adopt this new sign-on process and only after that, convincing the average American patient to sign up and use it without these credentials losing practical meaning.

b. How would requiring digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 CSPs) impact cybersecurity and data exchange?

NIST 800-63-3 IAL2/AAL2 CSPs have the potential to increase the security of the health IT ecosystem due to their enhanced identity validation features at point of log-in and by reducing the total number of passwords that are at risk of exposure throughout the ecosystem (as patients would no longer need unique passwords for each provider portal that they are accessing). However, if the CSP digital identity credential or system is compromised, then there is an enhanced risk that all the person's health data could be exposed to bad actors (foreign or domestic hackers or even unauthorized family members).

Likewise, simplicity of enrollment and ease of use are vital. Without that, there is a risk of these credentials being so difficult to obtain, produce, or remember when attempting to sign in that the patients with the most to gain from this initiative never use it. This could result in perhaps the highest risk – patients re-using lower security passwords across multiple sites, which creates the highest risk of breach and data exposure.

c. What impact would mandatory use of the OpenID Connect identity protocol have?

Mandating support for the protocol most likely requires significant financial investment from all sorts of health app vendors to comply. Additionally, there will always be some patients who are unable or unwilling to use digital identity and they still have a right to access their electronic health records.

3. Technical Standards and Certification

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

CMS can encourage the use of open, standards-based, publicly available APIs by reinforcing compliance through certification and reimbursement incentives tied to standards like FHIR, public documentation, and conformance to HL7 profiles, and require it for APIs used in CMS programs. CMS can also discourage proprietary endpoints in procurement and interoperability evaluations.

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?

A nationwide provider directory of FHIR endpoints is a critical missing component that can significantly accelerate the evolution of the health IT ecosystem towards the goal of high-connectivity and data transparency while reducing burdens for access and common transactions for all participants. This directory is foundational to accelerating secure, scalable health data exchange. From a health IT vendor's standpoint, the availability of such a resource will directly improve the utility and reach of digital health applications serving patients, providers, and payers.

Potential improvements include the following:

- *Streamlined Data Exchange and Interoperability*—A comprehensive FHIR endpoint directory enables automated discovery of where and how to access clinical data

across organizations, which is critical for use cases such as transitions of care, patient-directed data access, and payer-provider data sharing.

- *Improved Patient Access to Longitudinal Records*—For vendors developing patient-facing apps (aggregators, PHRs), a directory makes it easier to locate the correct endpoint associated with a patient's provider or health system—reducing manual entry, latency, and fragmentation.
- *Efficient Integration for Developers*—With consistent metadata about each FHIR endpoint (organization, capabilities, version, security protocols), developers can reduce the time spent configuring integrations and testing endpoint availability, significantly lowering implementation costs.
- *Accelerated Compliance with CMS and ASTP/ONC Interoperability Rules*—A centralized, authoritative directory simplifies compliance with CMS and ASTP/ONC rules that require endpoint publication, helping payers meet technical requirements more efficiently and securely.
- *Support for Public Health and Emergency Response*—In times of public health emergencies, being able to programmatically locate and connect with provider FHIR endpoints nationwide allows for rapid deployment of alerts, surveillance queries, and care coordination.
- *Improved Services and Efficiencies for Payers*—Maintaining accurate FHIR endpoint directories is currently a fragmented and burdensome task for payers, leading to failed transactions and higher administrative costs. A nationwide provider directory with secure, up-to-date FHIR endpoints—ideally with provider self-service capabilities and public access—will streamline automation, reduce costs, and improve data accuracy and accessibility for all stakeholders. See response to PA-4 for more details.

Who should publish and maintain such a directory?

InterSystems recommends a federated governance model with centralized oversight for the directory. ASTP/ONC or CMS can serve as the national convening authority (either directly or through a designated entity), setting technical standards and certification criteria to ensure quality and consistency. The directory infrastructure can be operated by a trusted non-profit or public-private partnership with strong developer and stakeholder engagement (Sequoia Project, CommonWell, or a designated TEFCA governance body). To ensure data accuracy, FHIR endpoint information will be submitted and updated through APIs by trusted sources, including EHR vendors, middleware providers, HIEs, health systems, and payers.

Should users bear a cost for accessing or using the directory?

The value of the nationwide provider directory of FHIR endpoints increases significantly if it is broadly adopted and used, a classic network effect. However, access and use charges for users present a significant barrier to the adoption of the directory, which in turn reduces the overall value and success of the directory. CMS can structure or encourage funding sources or cost-sharing mechanisms that will support broad adoption and use of the directory.

A national FHIR endpoint directory is a foundational asset for real-world interoperability. It directly reduces the cost and complexity of exchanging health data, drives adoption of FHIR APIs, and enables patients to better control and access their health information. CMS and ASTP/ONC can lead its creation, ensure its openness, and maintain it as a public good.

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

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

b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?

c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?

d. Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?

InterSystems recognizes the value USCDI provides by creating a foundational set of standardized data elements that enhance baseline interoperability across healthcare systems. By establishing a common starting point, USCDI significantly contributes to improved data exchange, enabling stakeholders to leverage standardized, structured data for critical clinical and administrative functions.

However, USCDI's current scope remains incomplete for many practical use cases, particularly in specialized clinical domains and administrative contexts. Data elements essential for nuanced care coordination, such as detailed imaging metadata, genomic information, comprehensive social determinants of health, behavioral health assessments, and specific device-generated data, are notably absent or inadequately represented. This limits the capacity of healthcare providers and payers to fully leverage interoperable data to deliver comprehensive patient-centered care.

Another substantial limitation lies in the variability of implementation. Even clearly defined USCDI data classes can face inconsistent interpretations across different health IT systems, leading to fragmented and unreliable data exchanges. For instance, critical elements like "disability status" or "functional assessments" may lack precise operational definitions, resulting in inconsistent implementation across health IT platforms. This undermines interoperability, reducing the effectiveness of the intended standardization.

To address these challenges, InterSystems suggests adopting a strategic, phased approach for expanding USCDI, prioritizing elements that deliver significant value without introducing unnecessary complexity. This expansion should be supported by robust and detailed implementation guidance developed collaboratively with industry stakeholders and standards organizations like HL7.

Lastly, a balanced approach to structured versus less structured data exchange is encouraged. While structured data remains critical for consistent, reliable interoperability, incorporating clinically rich narrative or less structured data, supported by advanced NLP,

substantially enhances data completeness. Such a hybrid strategy ensures comprehensive patient records without sacrificing interoperability or data quality.

TD-9. Regarding certification of health IT:

a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?

Prioritizing API-enabled capabilities over specific software functionality, including within certified electronic health record technology (CEHRT), helps ensure consistent API certification across the health IT ecosystem. This approach allows ASTP/ONC and the CEHRT process to align with open industry standards and widely accepted community practices where appropriate.

b. What would be the drawbacks?

c. How could ASTP/ONC revise health IT certification criteria to require APIs to consistently support exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data)?

To help promote consistent support for API exchanging data from all aspects of the patient's chart, revise the IT certification to broaden data exchange criteria to include APIs for contributing unstructured data in the form of binary streams (images or PDFs). Technologies like OCR and image recognition can render this unstructured data into computable data, which in turn allows the application of AI and NLP processes to categorize information and generate insights.

d. What policy changes could CMS make so providers are motivated to respond to API- based data requests with best possible coverage and quality of data?

Mandate that Medicare payment claims need to be accompanied by their corresponding digital encounter records (including image files and documents, where electronic records are not available).

TD-11. As of January 1, 2024, many health IT developers with products certified through the ONC Health IT Certification Program are required to include the capability to perform an electronic health information export or "EHI export" for a single patient as well as for patient populations (45 CFR 170.315(b)(10)). Such health IT developers are also required to publicly describe the format of the EHI export. Notably, how EHI export was accomplished was left entirely to the health IT developer. Now that this capability has been in production for over a year, CMS and ASTP/ONC seek input on the following:

a. Should this capability be revised to specify standardized API requirements for EHI export?
b. Are there specific workflow aspects that could be improved?
c. Should CMS consider policy changes to support this capability's use?

EHI export is a valuable function to be further developed, and CMS and ASTP/ONC can work with HL7 to define a FHIR-based standardized EHI Export API specification that extends FHIR Bulk Data Access and SMART on FHIR to EHI export. This ensures consistent data structure and semantics, enables scalable, secure access to both individual and population-level data, and fosters easier incorporation into third-party apps, analytics tools, and

patient-controlled data platforms. Further, CMS can implement policy enhancements to promote effective use of EHI exports by:

- Aligning incentives with value-based care, care transitions, and social determinants documentation
- Encouraging TEFCA and QHIN participation to ensure secure and standardized data exchange
- Improving certification transparency by requiring public API documentation and tracking real-world export usage
- Educating Medicare beneficiaries on how to access and use their health data through third-party apps and platforms

4. Data Exchange

TD-12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?

CMS should endorse non-CMS data sources and networks that meet rigorous standards of interoperability, data integrity, privacy, and utility. Such endorsement accelerates innovation, reduces data fragmentation, and supports ecosystem-wide trust and alignment. However, it is important that such endorsements be based on neutral, transparent, objective criteria and metrics to ensure a level playing field for all participants in the ecosystem.

By endorsing high-value non-CMS data sources and networks, CMS expands the health data landscape in a structured and scalable way. A formal endorsement framework—grounded in standards, transparency, and demonstrable impact—empowers developers to build more effective, interoperable, and equitable health IT solutions.

Why CMS Endorsement Matters

As a health IT vendor, InterSystems often needs to integrate data from multiple sources—public and private—to deliver accurate, timely, and actionable tools and information. Endorsements from CMS:

- Signal data trustworthiness to developers, providers, and payers
- Reduce integration overhead by highlighting pre-vetted networks or data sources
- Encourage alignment with federal standards, especially for APIs and security
- Create a more level playing field for innovators, especially smaller vendors who depend on predictable, high-quality data access

The following are examples of data sources and networks that CMS can consider endorsing:

- TEFCA QHINs
- National or regional HIEs with FHIR-based APIs
- Prescription drug monitoring programs (PDMPs) with open API access
- Private payer APIs that support patient and provider interoperability

- Social service resource networks (SDOH platforms) using HL7 Gravity standards
- Datasets from which we can infer socioeconomic status (SES), that is, publicly available housing data (urban vs, rural census, density, commuting distance), environment data (air quality), etc.

Recommended Criteria for CMS Endorsement

We propose that CMS evaluate non-CMS data sources and networks using a transparent, metrics-based framework that prioritizes the following:

Standards Conformance and Interoperability

- Compliance with HL7 FHIR, USCDI, SMART on FHIR, and TEFCA standards
- Support for standardized API endpoints and OAuth 2.0/SMART authentication
- Real-time or near real-time data exchange capabilities

Data Quality and Integrity

- High data completeness and accuracy across domains (diagnoses, procedures, medications); data is not only present but conforms to the relevant form
- Proven governance and provenance tracking to ensure source reliability
- Deduplication and reconciliation processes to reduce noise

Privacy, Security, and Consent Management

- Alignment with HIPAA, 21st Century Cures Act, and applicable state laws
- Patient-centered consent models with transparency and revocability
- Secure, role-based access and audit trails

Network Participation and Coverage

- Breadth and diversity of participants (rural/urban, multispecialty, payer mix)
- Inclusion of underserved and high-risk populations to avoid data bias
- Cross-sector interoperability (payer, provider, public health, social services)

Demonstrated Utility and Use Case Support

- Evidence that the data and network support value-based care, care coordination, patient access, or public health
- Developer adoption metrics (SDKs, sandbox usage, documented APIs)
- Case studies or measurable impact on health outcomes or efficiency

Transparency and Public Access

- Public documentation of APIs, endpoints, and data dictionaries
- Open or low-barrier access for authorized users

TD-15. Regarding bulk FHIR APIs:

a. How would increased use of bulk FHIR improve use cases and data flow?

There are several advantages of using bulk FHIR:

- *Enabling scalable analytics and population health:* bulk FHIR APIs allow entire datasets (patients with a condition, encounters over a period) to be exported

efficiently, supporting public health surveillance, predictive modeling, and outcomes research.

- *Streamlining data exchange across organizations:* bulk exports can be scheduled or triggered for partner organizations, payers, or research collaborators, facilitating secure and efficient data sharing at scale.
- *Reducing load from repetitive queries:* instead of issuing thousands of synchronous FHIR read queries (per patient, for example), one export job retrieves the entire dataset in batches, lowering system strain and improving throughput.
- Easy data migration from legacy FHIR Servers.

b. What are the potential disadvantages of their use?

The potential disadvantages of using bulk FHIR include:

- *Resource-intensive operations:* bulk exports can be CPU- and I/O-intensive, especially when exporting millions of records. Without proper scheduling and throttling, they may impact system performance.
- *Standard limitations:* the FHIR Bulk Data specification (Flat FHIR/NDJSON) is designed for exports, not for transactional updates or near-real-time workflows. As a result, it is not ideal for interactive or incremental use cases.

5. Compliance

TD-18. Information blocking:

a. Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?

InterSystems has no direct knowledge of acts of information blocking by our clients or users. InterSystems technology is specifically designed to facilitate and support the free and smooth flow of information within and between data systems and organizations. InterSystems HealthShare and InterSystems IRIS for Health directly address potential data sharing challenges and help prevent inadvertent data blocking by:

- Enabling standards-based interoperability (FHIR, HL7, CDA) to ensure usable, complete data exchange
- Supporting real-time API access and longitudinal patient records to reduce non-responsiveness
- Providing audit trails and consent management, helping organizations demonstrate compliance
- Powering HIEs and TEFCA-ready networks, ensuring data is shared across systems and regions

These tools assist healthcare organizations in avoiding information blocking violations while improving care coordination and patient access.

F. Value-Based Care Organizations

As a technology vendor, InterSystems is providing responses to selected items in this section based on value-based care organization customer experiences.

1. Digital Health Adoption

VB-3. What are essential health IT capabilities for value-based care arrangements?

a. Examples (not comprehensive) may include: care planning, patient event notification, data extraction/normalization, quality performance measurement, access to claims data, attribution and patient ID matching, remote device interoperability, or other patient empowerment tools.

Value-based care arrangements thrive in an environment where provider and payer incentives are aligned and where data and information can be shared. In that spirit, health IT capabilities that support value-based care arrangements include:

- Supporting integrated care through unifying data and making it available to clinicians
- Navigating care through analytics and clinical notifications to care teams
- Promoting self-care by offering digital front door capabilities that enable a patient to be an active participant in their care team
- Care planning and coordination to ensure that members of a care team can interact with one another to deliver care efficiently and eliminate duplicative testing while ensuring that gaps are closed in a low-cost way

b. What other health IT capabilities have proven valuable to succeeding in value-based care arrangements?

Proper patient and provider attribution dictates that identity management of both patient lists and provider credentials within a network are maintained and updated regularly. To achieve this, a robust enterprise master patient index is essential.

2. Compliance and Certification

InterSystems is not responding to any items in this section.

3. Technical Standards

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?

For claims that require a longitudinal record of diagnoses, medications, treatments administered previously, etc. for a single patient, a FHIR-based repository of clinical data by provider might facilitate electronic prior authorization, claims processing, and other payer activities. A key element is high trust in identity data resolution to ensure the ecosystem is providing only data for the member in question who has authorized such a transaction as part of the claims process.

To be truly effective, a FHIR endpoints directory must:

- Facilitate discovery (who is available)
- Support connection (how to connect)
- Ensure trust (are they legitimate and secure)
- Enable interoperability (what data can be exchanged)

The following table summarizes the endpoint directory data elements necessary to maximize the effectiveness of a nationwide provider directory.

Element	Description
Core Data Elements	
Endpoint Identification	• Endpoint ID: Unique identifier for the FHIR endpoint (UUID) • FHIR Endpoint URL: The base URL where the FHIR server is accessible • Endpoint Name: Human-readable name of the endpoint
Organization Information	• Organization Name: Legal name of the entity operating the endpoint • Organization ID: NPI, OID, or other authoritative identifiers • Contact Information: Email, phone number, technical contact details • Organization Type: Hospital, clinic, payer, HIE, vendor, etc.
Endpoint Technical Details	• FHIR Version Supported: R4, R5 • Supported Resources: List of FHIR resources available (Patient, Observation) • Security Protocols: – OAuth 2.0 / SMART on FHIR support – TLS version used – Public keys/certificates (if applicable) • Authentication Requirements: Type of authentication required (client credentials, API key, etc.)
Operational and Metadata Elements	
Geographic and Jurisdictional Context	• Location/Region: State, city, or service region • Jurisdictional Authority: Relevant health authority or regional HIE
Capability Statement	• FHIR CapabilityStatement URL: Link to server metadata about supported interactions and profiles. • Last Validated Date: When the endpoint's availability and configuration were last confirmed
Endpoint Status and Availability	• Endpoint Status: Active, inactive, testing, deprecated • Uptime History / SLA: Optional but valuable for high-reliability services
Interoperability and Use Case Metadata	
Exchange Use Case	• Purpose of Use: Treatment, patient access, payment, public health, etc. • Exchange Framework Participation: TEFCA, Carequality, CommonWell, etc.
Data Access Policies	• Access Restrictions: Jurisdictional, organizational, or user-level limits • Privacy & Consent Models: Requirements for patient consent or data sharing agreements
Governance and Provenance	

Element	Description
Source and Provenance	• Submitting Entity: Who provided the endpoint data. • Date Submitted/Updated: Time of record creation or last update • Verification Status: Whether the endpoint has been verified and by whom
Optional Enhancements	
Service Tags / Taxonomy	• Tags or Classifications: for example, "EHR Vendor", "Lab Data Exchange", "Public Health Reporting"
APIs Beyond FHIR	• Other API Types: Inclusion of legacy HL7 V2, CDA, Direct messaging endpoints if relevant

InterSystems In the Health IT Ecosystem

InterSystems technology is embedded throughout the U.S. and global health IT ecosystem. InterSystems technology manages more than 1 billion health records across the world and is used by 100% of the hospitals on the U.S. News & World Report Honor roll. InterSystems has connected to and integrated nearly 200 different health information systems, including those of EPIC, Cerner, and Allscripts. InterSystems HealthShare supports several of the country's leading HIEs, covering more than 40 percent of the U.S. population.

InterSystems supports the health IT ecosystem through platforms like InterSystems IRIS for Health and InterSystems HealthShare, which includes modules like Personal Community, Provider Directory, and InterSystems EMPI that provide functionality essential to building a truly connected health ecosystem for patients, caregivers, providers, payers, and government.

Foundation of Health Information Exchange

InterSystems technology, including InterSystems IRIS for Health and HealthShare, provide the essential foundation for health information exchange. Interoperability and digital information exchange technologies are required to enable secure, standardized, and efficient health information sharing across systems, stakeholders, and settings of care. At a basic level, health information exchange infrastructure supports the real-time, bi-directional exchange of clinical and claims data between payers, providers, and patients and the move in recent years to establish TEFCA means that regional HIEs will play an important role by participating as QHINs in TEFCA networks.

Core technologies required to facilitate health information exchange include:

- **Standardized health data models** that ensure exchanged data is interpretable and usable across systems and applications. Current standards include USCDI, HL7 CDA, C-CDA, and X12, but FHIR is poised to emerge as the backbone of modern health data exchange.
- **Terminology management** supports the use of standard (LOINC, SNOMED, ICD-9/10, CPT, NIST) and custom code sets by enabling the creation, import, and runtime application of translation maps. APIs, lookup tables, or native tools can be used to normalize data and apply terminology mappings. These services ensure efficient, reliable integration with third-party solutions for managing and maintaining code sets and translations.
- **Identity management** is required to reconcile and link person records across disparate systems. In the context of health information exchange, person records typically equate to patient records, but the concept of identity management applies more generally to resolving the identities of patients, beneficiaries, claimants, providers, and other entities.
- **Data aggregation and normalization** is required to unify and transform claims and clinical data from disparate sources into standardized formats for analytics and decision support.
- **Electronic medical record (EMR)** integration requires that EMR systems support certified APIs to integrate external data seamlessly and to support clinical workflows.

- **Consent management** enables patients to control which entities can access their health data and ensures that data sharing meets compliance requirements in conformance with patient directions.
- **Data security and privacy** is required to meet HIPAA compliance and cybersecurity requirements. Technologies include encryption, audit logging, intrusion detection, and data loss prevention.
- **Identity and Access Management (IAM)** ensures that patients and providers access only data that they are authorized to view. Required capabilities include identity verification, authentication, and authorization frameworks such as OAuth 2.0 and OpenID Connect.

Together, these capabilities enable sharing health data across systems, stakeholders, and settings of care. InterSystems technology provides or supports this full range of functionality.

Health Information Exchanges

InterSystems technology underpins the operations for many of the nation's largest HIEs as shown in the following table.

State	Organization	Patients (millions)	Connections
Alabama	One Health Record (ALOHR)	5.1	767
California	Manifest MedEx (MX)	39.0	500
Georgia	Georgia Health Information Network (GaHIN)	10.9	(In progress)
Michigan	MiHIN – Great Lakes Health Connect (GLHC)	10.0	130
Missouri +	MHC – Velatura HIE	12.0	515
Montana	Big Sky Care Connect (BSCC)	1.1	75
Nebraska	CyncHealth	2.0	230
New York	Healthix	21.0	1200
New York	Hixny	1.7	1300
North Carolina	NC HealthConnex (NC HIE)	10.7	350
Pennsylvania	PA Patient & Provider Network (P3N)	13.0	100
Tennessee	East Tennessee Health Information Network (etHIN)	7.1	104
Texas	Greater Houston Healthconnect (GHHC)	20.0	480

Interoperability with National Networks

InterSystems is a strong advocate for nationwide interoperability and supports participation in networks like:

- TEFCA QHINs
- eHealth Exchange
- Carequality
- CommonWell Health Alliance

Our platforms are TEFCA-ready and enable organizations to connect with these networks while maintaining local control and data governance. We help HIEs, health systems, and payers translate national standards into local impact, ensuring that data flows securely and meaningfully across the care continuum.

Relationship with Payers, Providers, and Others

InterSystems acts as a neutral data broker that facilitates collaboration between payers, providers, public health agencies, and community organizations. Our technology supports:

- Payer-provider data exchange for risk adjustment, care management, and quality reporting
- Public health reporting for immunizations, syndromic surveillance, and disease registries
- Consumer access through patient portals and third-party apps using FHIR APIs

By enabling bidirectional, standards-based exchange, we help stakeholders align around shared goals, better outcomes, lower costs, and improved patient experience.

Addressing Waste, Fraud, and Abuse

Waste, fraud, and abuse cost the U.S. healthcare system billions annually. InterSystems helps combat this through:

- Data integration and normalization to detect anomalies across claims, clinical, and social data
- Integration with real-time analytic tools that can be used to flag suspicious billing patterns or duplicate services
- Audit trails and consent management to ensure transparency and accountability

Our platforms empower payers and regulators to identify and act on fraud signals faster, reducing financial losses and protecting patient trust. By integrating InterSystems technologies into the internal CMS Fraud, Waste and Abuse systems, the agency can realize significant reductions in the prevalence of this activity.

Enabling Payer-Provider Collaboration

True value-based care requires deep collaboration between payers and providers. InterSystems supports this collaboration by:

- Creating shared care plans accessible to all stakeholders
- Enabling risk stratification and predictive modeling using unified data
- Supporting prior authorization automation and quality measure reporting

By breaking down data silos, InterSystems helps payers and providers move from transactional relationships to strategic partnerships focused on outcomes.

InterSystems OMOP: Enabling Research and Regulatory Alignment

InterSystems OMOP (Observational Medical Outcomes Partnership) enables organizations to transform their data into the OMOP Common Data Model, a global standard used for real-world evidence, clinical research, and regulatory reporting. This solution enables:

- Standardized analytics across diverse datasets for population health and clinical trials
- Participation in research networks like OHDSI (Observational Health Data Sciences and Informatics)
- Regulatory compliance with FDA and CMS initiatives that require real-world data in OMOP format

By integrating OMOP capabilities into our platforms, InterSystems empowers healthcare organizations to leverage their data for discovery, innovation, and policy alignment.

Conclusion

InterSystems is committed to building a health technology ecosystem that is interoperable, intelligent, and inclusive. For more than 47 years, we have led healthcare interoperability and are the market leader. Payers, providers, HIEs, and national networks rely on InterSystems technology to support two-thirds of all healthcare transactions in the U.S. We are integral to the health technology ecosystem and are the fabric that binds it together. We believe CMS should continue to lead by setting clear standards and aligning incentives, while also empowering the private sector to innovate. By supporting national networks, closing Medicaid gaps, enabling OMOP-based research, and fostering payer-provider collaboration, CMS and technology partners like InterSystems can drive a more connected, equitable, and efficient healthcare system.