June 16, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Dr. Thomas Keane
Assistant Secretary for Technology Policy
Acting National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, D.C. 20201

Re: Request for Information – Health Technology Ecosystem (CMS-0042-NC)

Submitted electronically via regulations.gov

Dear Dr. Oz and Dr. Keane,

STChealth is a public health and population technology-intelligence company dedicated to transforming population health data systems into integrated networks, enabling informed decision-making in real-time. Our mission is to eradicate preventable disease through connected intelligence. With over three decades of experience, STChealth is a trusted partner in public health and is recognized as the private sector thought leader in the Immunization Information System (IIS) industry.

Our legacy began with the creation of the first jurisdictional immunization system, and that foundation has grown into the nation's most comprehensive Vaccine Intelligence™ network. The STChealth network connects tens of thousands of key stakeholders across the IIS ecosystem, including state public health systems, pharmacies, providers, schools and more. We understand the critical need for accurate, secure, high-quality data and seamless interoperability to ensure real-time access to actionable information which ultimately improves outcomes, reduces costs, and enables patients to make the best healthcare decisions for themselves and their families.

STChealth has achieved countless "firsts" in the IIS infrastructure community. Our solutions have supported public health not only in routine immunization operations but also during emergencies such as bioterrorism threats, natural disasters, pandemics, and outbreaks. In 2005, we launched the first multi-state immunization data exchange in response to Hurricane Katrina. In 2009, we were the first to connect pharmacies to IIS during the H1N1 response. During the COVID-19 pandemic, our national immunization exchange network provided critical vaccine intelligence local public health, CDC and the White House COVID Response Teams. Today, this network includes over 60,000 community pharmacies, medical facilities, clinics, schools, and consumers, all with access to immunization data across the U.S.

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A powerful example of our community impact is our collaboration with pharmacies during their nationwide Wellness Days. These events offer free health screenings and immunizations to communities, especially underserved populations. STChealth's infrastructure enables real-time data capture and reporting from these events (often servicing over 300,000 patients in a single day). Our technology ensures complete data capture along with sharing of reportable data to public health. This partnership demonstrates how pharmacies, empowered by STChealth's technology, are expanding access to preventive care and strengthening community health.

Our response to this Request for Information is intended to highlight the critical role of the ecosystem partners we serve and the importance of taking the specific dynamics of this part of the healthcare market into consideration when considering new policies, initiatives, and standards.

63 jurisdictions designated by the Centers for Disease Control and Prevention (CDC) operate an IIS, including every state as well as many territories and some local governments. These systems serve multiple critical functions within public health and the broader health care ecosystem. They enable the exchange of vaccine and immunization data essential both at the point of care and in surveillance and epidemiological research; they support efforts to fight infectious diseases such as the measles outbreaks, we are currently experiencing across the nation; and they have in many cases begun to produce efficiencies and cost savings by their utility in other areas, such as chronic disease and environmental health.

Many IISs are statutorily mandated, and some have been in operation for more than 25 years. During the COVID-19 Public Health Emergency these systems rapidly expanded, supporting a surge in data connections, exchange partners, and transaction volumes. As a result, they have grown to represent some of the nation's most robust and effective health data exchanges. Each year, more than one billion secure health data transactions occur between jurisdictional IISs and health systems, pharmacies, Health Information Exchanges, Federally Qualified Health Centers, and other providers. Their utility extends into non-traditional health care settings, and these functions are carried out more cost-effectively than many comparable systems in the health and human services sector. Nearly two-thirds of all IISs are operated by state health agencies in partnership with private sector companies who provide Software-as-a-Service (SaaS) based, cloud hosted secure platforms as well as consumer-facing applications to enable patient access.

Immunization Information Systems are not static, research-based platforms designed solely for academic purposes. They are dynamic, robust healthcare systems that ensure accurate, timely, and secure vaccine data for patients and their families, preventing over-vaccination and improving health outcomes. This is an essential part of the health data exchange universe that is often overlooked.

In the current health data exchange ecosystem, many gaps exist as pharmacies and non-traditional providers have largely been overlooked and are often seen as an afterthought. Pharmacies are the providers most frequented by patients with an average of 30 visits per year, versus 1-2 visits per year for primary care and 5-6 visits per year for specialty care. Pharmacies are also often the most accessible source of healthcare, with over 90% of patients living within 5 miles of a pharmacy. Greater leveraging of the health data available through pharmacies should be a focus of any efforts to improve interoperability, patient empowerment, and efficiency within the system.

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Further, we would strongly advocate that CMS take aggressive actions to improve coordination between the programs it administers and those of its sister agencies including CDC, HRSA, and eventually AHA. Public health data systems including IIS are key sources of information which enable better outcomes and support the meeting of clinical and quality standards such as HEDIS and EPSDT. The growth of these systems to include other data sets and conditions such as chronic disease offers significant value in the future. This data has value for both Medicare and Medicaid populations, yet efforts to coordinate are often "ad-hoc" and are hampered by lack of clear guidance and processes that are not tailored to these use cases.

Within the Medicaid program, while some state Medicaid agencies are coordinating with their public health counterparts, many of our public health partners experience great difficulty in attempting to establish those partnerships. The information available within IIS is critical to HEDIS compliance for Medicaid managed care plans nationally, yet the landscape of connectivity for these plans is scattered, with many creating individual and often inefficient connections. Most state public health administrators have little knowledge of Medicaid program policies or processes, and clear guidance has not been issued to assist Medicaid staff in structuring these partnerships. A streamlined and well-defined process with a tailored APD structure, standard cost allocation methodology, and clear guidance from CMS would help alleviate the barriers and enable greater value creation and cost efficiency in this area.

We hope that our thoughts here and our perspective provided in response to the specific questions asked below is valuable to CMS leadership, and we very much appreciate the innovative and inclusive approach that is being taken, We would welcome the opportunity to discuss these ideas and suggestions further with the appropriate staff in the future.

Sincerely,

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Specific Questions and Responses

Question: PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers or both?
Response: Immunization data has long served as the gold standard for real-time, accessible health information for both caregivers and patients. Immunization systems—largely operated at the state level—have historically driven interoperability efforts due to their direct connection to population health outcomes. STChealth believes that ensuring providers, patients, and others in the healthcare ecosystem have timely access to this data is critical for ongoing patient care. It is equally important to prevent over-vaccination as it is to ensure a patient's full protection. This proven model offers a strong foundation for expanding into additional use cases that can further improve patient outcomes, while ensuring caregivers have the essential information needed to deliver optimal care.

Question: PC-8c. What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?
Response: Healthcare operates in segmented environments—pharmacy, medical, dental, alternative care, public health, Medicaid, Medicare, and commercial insurance—each with distinct workflows and incentives. STChealth recommends that existing standards continue to be applied within each domain based on its specific use case and outcomes. HHS should focus on empowering public health and Medicaid agencies to translate and align these standards across sectors for specific groups and use cases. This approach would support a more complete picture of the patient without disrupting established best practices within each group or data source.

Question: 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:
Response: STChealth has participated in FHIR code-a-thons and related activities; however, we have not encountered a defined use case that required FHIR to achieve production-level outcomes. Based on our experience with interoperability across various public health data sets—including immunization, disease and case reporting, lead screening, oral health, and health risk indicators such as BMI and cholesterol—we believe it is essential to build upon existing, effective data exchange models rather than introducing new standards for use cases that are already well-supported. In our one-to-one comparisons of current public health data flows with FHIR-based equivalents within STC's public health network, we found that FHIR payloads are significantly higher. This increase in data volume can lead to higher infrastructure and data costs, in addition to the ongoing expense of adapting systems to evolving standards versus taking a patient and population health outcome approach to data exchange. Rather than a "rip-and-replace" approach, we recommend selecting the most appropriate standard for each specific use case. The primary goal should be to make data actionable to improve patient and population health outcomes. Just as modern tools can translate languages with ease, today's technology also enables translation between data standards. Therefore, STChealth suggests that HHS focus on equipping public health and Medicaid/Medicare agencies to serve as translators across standards, while also considering the long-term operational costs associated with implementing each standard.

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Question: PR-5 g. Bulk FHIR – Do you support Group ID-based access filtering for population-specific queries?
Response: The ability to support bulk data exchange is critical for use cases that fall outside of point-of-care workflows. While FHIR may be one viable approach, STChealth recommends also considering other established methods already widely adopted across the industry. FHIR Bulk methods should be prioritized for new use cases or where no simpler, more cost-effective solution exists. This approach ensures flexibility and efficiency without imposing unnecessary burdens on existing systems.

Question: PA-5a. How interested are payers and providers in EHR technology advances that enable bulk extraction of clinical quality data from EHRs to payers to allow them to do the calculations instead of the provider-side technology?
Response: As an immunization information system vendor working closely with pharmacies that provide clinical care, STChealth frequently receives requests from payers to access data in bulk to support HEDIS and other clinical quality measures. These requests come not only from commercial payers and Managed Care Organizations (MCOs) but also from Medicaid programs—often the largest payer in a state. In evaluating standards for data exchange, it is essential to consider both the technical feasibility and the long-term operational costs of maintaining those standards. Equally important are the policy barriers that may restrict data sharing between stakeholders. STC recommends that HHS support the use of effective, efficient standards tailored to specific care models, while also addressing policy and infrastructure needs that enable secure, sustainable data exchange across the healthcare ecosystem.

Question: 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?
Response: Both public health Immunization Information Systems (IIS) and pharmacy clinical systems require direct support to ensure alignment with Medicaid and Medicare beneficiaries. For public health, it is essential to sustain and expand connections with care providers and community resources that serve these populations. This includes enabling both real-time and bulk data exchange, while also supporting enhancements to improve usability and enhanced data quality. Although Medicaid match programs exist to support public health, their implementation is often subject to interpretation by individual states or regional offices. To streamline this process, STChealth recommends that HHS provide standardized templates, clearer guidance tied to specific outcomes, and a unified methodology for defining match criteria based on the populations served. This would promote a more consistent, effective, and efficient approach across jurisdictions.

Question: TD-2b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?
Response: Ensuring that public health agencies and pharmacies can access accurate patient-level, Electronic Health Record (EHR) data at the right time is critical to delivering effective patient care for both of these ecosystems. This includes access to immunization records, diagnoses, lab results, and medication histories. Equally important is the ability for public health and pharmacy systems to share this data back with primary care providers to support continuity of care. This bidirectional exchange enables public health programs to collect, analyze and monitor health trends, respond to

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emerging issues, and implement timely interventions. Integrating these data sources with tools like Blue Button 2.0 further enhances population health monitoring, disease surveillance, and care coordination across the healthcare system—while maintaining alignment with national data standards.

Question: TD-2c. What obstacles prevent accessing these data sources today?
Response: There are two primary challenges, one policy-related and the other technical. On the policy side, our experience is that healthcare providers are often not incentivized to share data with public health authorities. STChealth recommends increased education and policy development, along with the creation of incentive models that encourage participation. Data sharing should be driven by clearly defined, mutually beneficial use cases—not simply for the sake of sharing – since having the correct data benefits everyone. On the technical side, the current token-based authentication method, which requires frequent renewal, presents a barrier to seamless data exchange. Addressing both the policy and technical hurdles is essential.

Question: TD-2d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?
Response: STChealth recommends that CMS and ASTP/ONC consider supporting APIs that use authentication keys as a more efficient and secure credentialing method for data exchange. This approach could streamline access while maintaining strong security protocols, ultimately encouraging broader adoption and innovation across healthcare systems.

Question: TD-3 a. What are the challenges and benefits?
Response: As a vendor operating statewide population health systems—including those serving over 10 million people—and managing a nationwide data exchange that supports over one-third of the U.S. population, STChealth views accurate patient matching as a foundational element of success. We recommend that patient matching use cases specific to public health systems be carefully considered, as these systems have unique workflows and patient journeys. Addressing these distinct needs is essential to ensuring the continued effectiveness and scalability of robust public health data networks.

Question: TD-4. How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?
Response: STChealth recommends including sample payloads and providing a Swagger document to clearly demonstrate how to interact with the Blue Button APIs. This would enhance usability and support more effective implementation by offering developers a practical reference for integration.

Question: 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?
Response: A directory of FHIR capabilities will only be effective if there are clear incentives and motivations for its use. STChealth recommends publishing endpoints for all actively used standards

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to support intended outcomes, while ensuring that new endpoints are designed with incentives in mind from the outset to help improve overall adoption.

Question: TD-6 a. What existing alternatives should be considered?
Response: One existing alternative to TEFCA that STChealth recommends is the Immunization Gateway (IZG). It has demonstrated success in enabling secure, standardized data exchange between immunization information systems and national partners and could serve as a model for broader interoperability efforts.

Question: TD-8. What are the most effective certification criteria and standards under the ONC Health IT Certification Program?
Response: The (f)(1) immunization certification criteria has been a resounding success. According to the most recent Immunization Information System Annual Report (2023 data, reported in 2024), there are 161,208 active HL7 2.5.1 connections. Based on STChealth's direct experience, the (f)(1) criteria have been a major driver in establishing this impressive number of direct connections. Additionally, ONC certification of EHR and pharmacy management systems for immunization workflows has spurred innovation and significantly improved data quality and usability across the ecosystem.

Question: TD-9 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?
Response: The success of the Meaningful Use program demonstrated that data sharing is achievable when supported by clear incentives. CMS could build on these lessons—both the intended outcomes and unintended consequences—to shape future policy. Expanding participation to include additional care providers, such as pharmacies and other key providers, and encouraging data sharing with public health and CMS programs would further strengthen the ecosystem. Motivating providers through aligned incentives and clearly defined use cases will help ensure high-quality, comprehensive data exchange.

Question: TD-12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?
Response: Yes, STChealth believes that CMS should consider endorsing non-CMS data sources and networks, provided they meet clear criteria. At a minimum, these entities should demonstrate a high level of trustworthiness, consistent service availability, and reliable uptime for their data offerings. Additional metrics could include adherence to national data standards, proven interoperability, and a track record of secure, privacy-conscious data exchange.

Question: TD-13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?
Response: Providing API access to a patient's complete electronic health information (EHI) opens the door to more comprehensive, outcome-driven care. It enables a full view of the patient's health journey, supporting efforts to prevent disease and improve care coordination. While not all data will be relevant for every use case, STChealth believes that having timely access to the right information

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empowers both human and AI-driven analysis to identify patterns, root causes, and opportunities for intervention. This can significantly enhance both individual and population health outcomes.

Question: TD-14 b. How are these connections established (for example, FHIR (g)(10) endpoints, TEFCA/Integrating the Health Enterprise (IHE) XCA, or proprietary APIs)?
Response: Connections are currently established using a variety of methods, including HTTPS, SOAP, and FHIR-based APIs. The choice of protocol often depends on the specific use case, system capabilities, and level of interoperability required.

Question: TD-17. Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?
Response: Public health has become an integral part of healthcare and data-sharing networks. To ensure the long-term viability of healthcare data networks, CMS and ASTP/ONC should provide sustained support to public health agencies, enabling them to adopt and maintain modern technologies. This includes funding and policy support for systems like Immunization Information Systems (IIS) to remain active participants in data sharing networks. Both CMS and ASTP/ONC can play a critical role in ensuring these systems are included in national strategies and resourced to contribute meaningfully to patient care and population health outcomes.

Question: 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?
Response: To address information blocking, CMS should consider standardizing data sharing agreements within programs under its jurisdiction. This would provide vendors with greater predictability and a clear framework for participation. Establishing consistent “rules of the road” can help reduce ambiguity and remove perceived policy barriers that often lead to non-responsiveness or incomplete data exchange.

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