November 20, 2026

Erica Schwartz, MD, MPH, JD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

Re: Data Intermediaries and Approaches to Strengthen Public Health Data Exchange Request for Information (CDC-2026-1519)

Submitted electronically via Regulations.gov

Dear Director Schwartz:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the "Data Intermediaries and Approaches to Strengthen Public Health Data Exchange" Request for Information (RFI) published in the Federal Register on September 21, 2026. We are pleased to submit comments to the Centers for Disease Control and Prevention (CDC) on this important topic.

WEDI was formed in 1991 by then Department of Health and Human Services (HHS) Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. Named in the Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the Secretary of HHS, WEDI is the leading multi-stakeholder authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI is recognized and trusted as a formal advisor to the Secretary. Our diverse membership includes health plans, providers, standards development organizations, health IT vendors, clearinghouses, federal and state government agencies, and patient advocacy organizations.

WEDI supports and shares CDC's goals of evaluating how data intermediaries can support secure, scalable, standards-based public health data exchange. Obtaining broad industry input allows critical stakeholders to share their experiences and perspectives in health data exchange, bringing a collaborative approach leveraging health IT to CDC's work with public health data intermediaries. Implementing standards and processes that encourage an effective and efficient exchange of health data will strengthen efforts to prevent disease, detect emerging threats, and reinforce the nation's public health systems.

Introduction

WEDI believes that trusted intermediaries, including health information exchanges (HIEs), health data utilities, Qualified Health Information Networks (QHINs), clearinghouses, Centers for Medicare & Medicaid Services (CMS)-Aligned Networks, and regional member-governed networks can play a critical role in the exchange of public health data. These entities carry administrative and clinical transactions for the health care industry connecting with most payers and providers in their region, which is the scale of public health needs. Achieving this vision requires a consistent foundation of standards, privacy and security protections, and purpose-driven data exchange, with a focus on leveraging existing infrastructure and avoiding duplicative systems and requirements.

We have seen the tangible benefits and a return on investment (ROI) in the use of current and proven standards for specific data exchange needs. For example, regional networks that have carried X12 transactions among payers and providers for decades have reduced per-transaction costs and now add Fast Healthcare Interoperability Resources (FHIR®)-based services, such as electronic prior authorization, on the same trusted connections. Any implementation of standards and operational changes, however, must account for differences in organizational resources, technical capabilities, and readiness. CMS and the Office of the National Coordinator for Health Information Technology (ONC) have considerable experience in identifying and requiring standards that support their health information exchange needs. CDC should coordinate with CMS, ONC, and other federal partners on common data exchange needs and the standards that support them, along with aligning regulatory requirements and compliance timelines, establishing a common implementation roadmap, and providing financial and technical assistance to small, rural, and under-resourced organizations.

Trust, governance, and accountability are essential to the success of health data exchange. CDC should consider strengthening the processes of vetting, onboarding, verifying, and monitoring its data intermediaries. Additionally, CDC should closely consider the Trusted Exchange Framework and Common Agreement™ (TEFCA®), overseen by ONC, in its work with data intermediaries.

Finally, WEDI supports federally backed pilot programs to test proposed standards, workflows, and implementation approaches before broader adoption. Pilots should evaluate not only technical performance but also workflow impacts, workforce burden, data usability, user experience, and ROI, with results made publicly available to inform future decisions. A “collect once, use many” approach should guide these efforts, enabling data generated during patient care to support multiple purposes. Through coordinated governance, targeted support, shared infrastructure, and evidence-based implementation, CDC can strengthen public health data exchange while improving efficiency and reducing burden across the health care ecosystem.

Summary of Key Points

The following is a summary of WEDI’s key points for public health data intermediaries and strengthening public health data exchange:

- CDC is urged to collaborate with its federal partners in the development of technical capabilities, infrastructure, governance, and resources that support a shared approach to public health data exchange.

- Alignment of a standard approach for public health data reporting and administrative and clinical data exchange is necessary to support data intermediaries, providers, health plans, clearinghouses, QHINs, and others, along with the need to transition at a pace that organizations can support and allows them to participate.

- Public health intermediaries should connect to the networks health care already uses, not build parallel ones. The cheapest and fastest data for public health is data that already flows for treatment, payment, and operations.

- Bi-directional data flow between public health data entities and providers and health plans is critical for developing a collaborative approach, well-rounded reporting, and mutual value in the use of public health data.

- Data sources, such as health plans and providers, and organizations that supply technology, clinical content, or decision-support tools to participants should not be treated as intermediaries unless they perform an intermediary function, such as routing, transforming, or disclosing public health data on behalf of other organizations.

Comments

A. Definition of Public Health Data Intermediary

A–1: How does this definition of ‘‘public health data intermediary’’ align or conflict with other established definitions, or on-the ground experiences, used across public health and health IT, and what changes would improve distinction or alignment?

WEDI comment:

WEDI has expertise in health data exchange for administrative and clinical care purposes. CDC's proposed definition of data intermediaries aligns with data exchange operations by HIEs, health data utilities, QHINs, and clearinghouses.

We believe that the proposed definition addresses critical aspects of health data exchange between organizations. Data intermediary organizations must be trusted through established and agreed upon standards and policies. The data exchange must be secured through appropriate privacy and security standards and technology. The exchange of data must be purpose-driven and meet the defined need for being shared with another organization.

WEDI suggests that:

1. The framework should distinguish data intermediaries from data sources, so health plans and providers that send or receive public health data are not treated as intermediaries solely for that reason. It should also clarify that a company that licenses clinical content,

guidelines, software, or decision-support tools to a participant is not a data intermediary unless it actually performs a defined intermediary function, such as receiving, routing, transforming, or disclosing public health data. Requirements should attach to the function performed and the data handled, not to a vendor's general role in the health care ecosystem.

2. The definition should distinguish network functions (routing, query, delivery) from service functions (translation, linkage, enrichment, analytics) and distinguish both from clinical content and decision-support services that do not handle public health data. These functions carry different risks, and governance should follow the function actually performed. CDC should clarify how the definition relates to existing HIPAA terms, such as health care clearinghouse and business associate, and to TEFCA roles. One organization may perform more than one role, but requirements should apply only to the relevant function and data flow; unclear overlap adds legal review cost and could sweep unrelated technology and content vendors into intermediary obligations.

B. Standards and Technical Capabilities

B–1: Which public health data capabilities, functions, and data sources (e.g., clinical, laboratory, claims, pharmacy, schools, social services) are data intermediaries currently supporting or well positioned to potentially support in the future? For which public health use cases do data intermediaries offer meaningful advantages over direct data exchange or other approaches? Where might the use of data intermediaries add unnecessary cost, complexity, latency, governance burden, or introduce risk? In your response, consider intermediary type, required technical and operational capabilities, and interoperability challenges, informed by: Public Health Data Modernization in Practice: Identification of Core Data Capabilities and Functions (https://cdn.ymaws.com/www.cste.org/resource/resmgr/logo/ identi_2__1_.pdf).

WEDI Comment:

Data intermediaries add the most value where many senders report to many jurisdictions, such as case reporting, laboratory reporting from small labs, and immunization queries. They add cost and risk when they insert an extra step into a working, high-volume direct feed. CDC should not require intermediaries where direct exchange already works. Payer and claims data is an underused source, although concerns about minimum necessary, patient consent and duplicate reporting of data will need to be addressed. Intermediaries that already carry X12 and FHIR payer transactions are well placed to deliver them within HIPAA's public health provisions.

B–2: With the proposed layered approach, which capabilities and standards should sit in the universal baseline versus service specific or use-case-specific profiles—for example: data quality/provenance (terminology normalization, record matching, longitudinal reconciliation, preservation of source values and transformation rules); exchange/routing (push/query/subscribe, bulk transfer, acknowledgments, jurisdiction-aware routing); security/trust (authentication, authorization, consent enforcement, auditability, incident response); and operational reliability (availability, latency, error rates, incident communication)? Please be specific about minimum requirements.

WEDI Comment:

WEDI fully supports and shares CDC's goals of leveraging health IT's advanced capabilities and functions to decrease burden and streamline processes to improve the quality of public health data exchange while minimizing administrative costs. Encouraging organizations to adopt and use a uniform set of standards is a key step toward enabling the efficient exchange of health information and the automation of public health workflows. In particular, real-time electronic transactions have the potential to decrease costs by reducing or eliminating manual processes (e.g., fax, phone, web portal) and improving the exchange of health data.

At a minimum, every intermediary should, for the functions it performs: (i) Preserve source values and maintain appropriate records of transformations; (ii) Acknowledge receipt and errors for each message with actionable error codes or a defined correction and resubmission process; (iii) Document applicable jurisdictional routing rules; (iv) Authenticate parties and maintain audit logs; (v) Provide security incident notice consistent with applicable law and contract; and (vi) Report service-level performance using defined, proportionate measures. Requirements should not compel disclosure of proprietary methods, algorithms, licensed content, or confidential security information. Normalization, record matching, query/subscribe, and consent services belong in service- or use-case-specific profiles and should apply only when provided by the intermediary.

Establishing Standards

To better achieve these goals, WEDI supports use of an appropriate standard for a specific data exchange need and believes the Health Level Seven (HL7) FHIR-based standards can support secure, scalable exchange. CDC should identify the specific federally adopted standard version, rather than simply the latest version, so requirements remain stable. FHIR, HL7 v2, and X12 will coexist for years. Translation among them is one way intermediaries create value, and funding and procurement approaches should account for that work. Standards-based interfaces should support interoperability while preserving vendors' rights in proprietary content, software, algorithms, and implementation methods; adoption of a standard should not require those materials to be open-sourced, transferred, or made available without appropriate license terms.

Organizations, regardless of their size and technical capabilities, need to be met where they are related to their capacity to support specific standards and should be supported as they transition over time to the single industry standard.

Currently, ONC and CMS are leveraging new standards and technologies, including FHIR, through regulatory requirements, industry pledges, and voluntary agreements. The Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity Final Rule reflects this transition by streamlining the ONC Health IT Certification Program while establishing a foundation for greater reliance on FHIR-based APIs. ONC has acknowledged that additional work is needed to advance FHIR specifications for certain use cases, as seen by the retention of certain public health certification criteria. ONC has recognized the continued reliance on existing standards and the need for further industry progress toward FHIR readiness. WEDI believes these considerations underscore the importance of aligning

certification requirements and implementation timelines with the maturity of available standards and the readiness of organizations to support them. While we work towards a single standard, it is important that CDC makes it accessible to ensure less resourced organizations can participate in health data exchange. This will help to ensure we have all the data points necessary for surveilling the health of our communities.

While the push to adopt new standards and technology will move the industry's health data exchange work forward, there is the potential for organizations to incur significant financial costs of supporting more than one standard during a transition period. Requiring stakeholders to support multiple standards simultaneously could have the unintended consequence of limiting participation. To minimize this, we urge the government to ensure all organizations have the resources and support to fully participate in public health data reporting.

We also urge impacted organizations to work together to create a unified, integrated, and agreed upon approach to move forward and establish a common exchange process implementation roadmap. Avoiding duplication of effort and eliminating the requirement to support multiple standards will result in increased participation in the exchange network and this in turn will lead to greater improvement in patient care delivery.

B–3: How should data intermediaries be assessed to determine whether they meet applicable capability, standards, performance expectations, security and data protection, and assessment of data quality? What standardized metrics, evidence, and testing approaches (e.g., conformance testing, certification, validation services) should be used, including to assess onboarding efficiency, scalability, and reach? What existing tools, programs, or approaches could be leveraged?

WEDI Comment:

As with the QHIN model, it is critical that a process be established to properly vet public health data intermediaries. Components of the QHIN process can be replicated for the data intermediaries, including completing a comprehensive application, onboarding, and ongoing monitoring processes. Onboarding should establish and evaluate the organization's capabilities to meet specified expectations for standards, performance, security, and data protection. Standardized metric reporting, conformance testing, certification, and validation services are all potential options that could be used to evaluate the capabilities and performance of participating organizations. A short monthly report from each intermediary would cover message volume, acknowledgment rate, error rate, median latency, uptime, and days to onboard a new sender. CDC should accept existing testing and accreditation results rather than create a new certification program and should not require repeat proof of controls already verified for QHIN or CMS-Aligned Network status.

CDC should also consider, as one option to explore, having data intermediaries function as a utility and managing them at the state level. This action could better establish commonalities, capabilities, and interoperability, data exchange, and privacy and security requirements. Any model should avoid requiring data sources to join multiple state networks and should avoid conflicting state-by-state requirements. Additionally, where states choose a utility model, it

should build on existing networks, keep participation open to any qualified intermediary on published terms, and not displace infrastructure that already works.

TEFCA and Security Issues

Security and trust must exist at each layer of health data exchange. ONC oversees TEFCA that establishes a framework for the trusted exchange of electronic health information. TEFCA seeks to advance interoperability across the nation's health care system in support of the access, exchange, and use of electronic health information in a secure and trusted manner. Data exchange through TEFCA is still evolving and should be evaluated for its ability to meet public health data intermediaries' needs.

QHINs are key components of data exchange through TEFCA, as they are the network-of-networks that enable nationwide exchange of health information. For a health information network to become a QHIN, they must complete a comprehensive application and review process, onboarding, and designation procedure and sign the Common Agreement. This process, however, is largely self-directed. Improvements in the review and onboarding processes will instill additional assurance for those seeking to leverage QHINs to exchange health data.

Prior to moving forward with a TEFCA and QHIN-based model for public health data exchange, we urge CDC to: (i) Develop a more thorough verification process that includes background checks and a rigorous review of organizational credentials; (ii) Establish a notification process to alert CDC if a data intermediary is found non-compliant or engaged in fraudulent activity; and (iii) Enhance monitoring of the use of data intermediaries and participant credentials. If fraudulent activity is detected, all parties must be contacted immediately, and appropriate action taken to protect patient data.

We urge CDC to also consider how the existing HIPAA privacy framework can be effectively leveraged to increase trust in public health reporting. A fixture in the health care system for more than two decades, patients rely on HIPAA to ensure that the confidentiality of their information is maintained. Ensuring that security and trust through compliance with applicable HIPAA requirements is maintained throughout public health data exchange by all participating parties will be critical to its success. We have consistently called on ONC and the Sequoia Project, as the Recognized Coordinating Entity® (RCE™), to explore requiring participants within the exchange environment to complete an appropriate and independent third-party privacy and security accreditation. We suggest that CDC explore requiring data intermediaries, not the data sources they connect, complete such accreditation. Participants that already comply with HIPAA do not need outside certification. Additionally, organizations complying with existing certification/accreditations, such as HITRUST certification, Systems and Organization Controls 2 (SOC 2) Type II reports, or EHNAC/DirectTrust accreditation, should be recognized as meeting the requirement.

B–4: How can a maturity model be useful for advancing data intermediary capabilities over time? If used, in what ways should a maturity model distinguish progression from minimum viable participation to repeatable production and advanced or adaptive capabilities? What capabilities or performance thresholds should characterize each

maturity level, and what evidence, including attestation methods, should be required for progression?

WEDI Comment:

WEDI supports the use of a maturity model to advance data intermediary capabilities over time, provided it establishes a clear, practical, and flexible pathway for organizations to participate and expand their capabilities as technology and industry needs evolve. As demonstrated by TEFCA, establishing a trusted framework for health information exchange is a crucial step toward advancing nationwide interoperability. A maturity model for data intermediaries could build on this foundation by defining progressively higher expectations for operational readiness, privacy and security, organizational accountability, and reliable data exchange. At the same time, the model should promote continuous improvement without creating unnecessary barriers to participation, duplicative requirements, or costs that could discourage organizations from participating.

A maturity model should distinguish broad stages of development by the data intermediary, such as:

- **Minimum viable participation**. Establish baseline requirements necessary for trusted exchange, including verified organizational identity and credentials, documented privacy and security policies, appropriate consent and authorization practices, and the ability to securely send, receive, and use data in accordance with applicable requirements.

- **Repeatable production**. Demonstrate that the capabilities operate consistently at scale, supported by documented operational procedures, credential monitoring, conformance testing, and measurable performance.

- **Advanced capabilities**. Recognize an organization's ability to continuously improve and respond to changing interoperability needs.

Progression between maturity levels should be based on objectively reviewed evidence rather than self-attestation. As stated, this could include independent third-party privacy and security assessments or accreditation (meeting the suggested requirements in B-2), documented organizational and credential verification, technical conformance and interoperability testing, operational performance metrics, and periodic reassessment. Attestation may be appropriate for selected lower-risk requirements, but it should be supported by documentation and subject to audit. More advanced levels should require stronger evidence that capabilities function reliably in production environments and that organizations can identify, address, and prevent recurring problems.

Finally, WEDI urges CDC to scale the requirements to an organization's role, size, and capabilities. The levels of the model should recognize meaningful progress without making the highest level a prerequisite for basic participation. Ultimately, a maturity model should strengthen trust and accountability while enabling broader participation, reducing duplicative effort, and improving the timely availability of appropriate health information for patients and

providers. Maturity levels should never be a condition for receiving data that providers are legally required to report.

B–5: How might artificial intelligence (AI) capabilities affect data intermediaries' technical, governance, and operational roles—including accelerating, replacing, or distributing functions?

WEDI Comment:

When an intermediary uses AI to process public health data, AI-generated codes, matches, or other inferences should be distinguishable from source values, with material transformations documented and outputs appropriately labeled. The intermediary should be accountable for errors attributable to its own AI-enabled processing, consistent with its role, control, and applicable law or contract. These expectations should not make a content or software vendor responsible for a participant's use of its licensed product or convert licensed clinical content into public data. CDC should align with applicable HHS-wide AI policy and avoid duplicative requirements.

C. Shared Infrastructure: Funding and Sustainability

C–2: What funding models are most likely to sustain and scale data intermediary services for public health over time? What factors most affect data intermediary costs and technical burden, and how should shared funding models account for differences in use, cost, and benefits across participants? Please provide examples from current practice where available.

WEDI Comment:

A blended model is most likely to last. Participation fees cover the infrastructure health care uses for its own purposes, and multi-year public funding pays for public health functions, such as routing to jurisdictions. Grant-only funding means features are built when grants exist and decay when they end.

C–3: How could funding models, fee structures, contract terms, or onboarding processes reduce financial barriers for rural providers, small laboratories, under-resourced public health jurisdictions, tribal entities, safety-net providers, and community based organizations? Please provide examples from current practice where available.

WEDI Comment:

Due to a lack of resources and technical capabilities, small, rural, and under-resourced provider organizations historically have experienced significant challenges optimizing health IT for the exchange of health information. This same need for technical assistance when the provider community was seeking to adopt the CMS Medicare and Medicaid EHR Incentive Programs (Meaningful Use, now Promoting Interoperability) was addressed by the establishment of financial incentives through the CMS Meaningful Use EHR Reporting Program. We urge CDC to

continue working with CMS to create additional incentives through existing programs to assist providers adopt the technology required to support public health reporting.

In addition, to advance public health reporting, we urge CDC to adopt the previous HHS policy of funding and deploying Regional Extension Centers (RECs). RECs offered technical assistance for smaller provider practices and those who provide primary care services in public and critical access hospitals, community health centers, and other settings to implement and maintain EHRs. RECs established themselves as trusted advisors for these smaller care settings and facilitated the effective use of health IT. The REC program was designed to leverage local expertise to provide practical, customized support to meet the needs of local health care providers. REC core service areas included: (i) EHR implementation and project management; (ii) Health IT education and training; (iii) Vendor selection and financial consultation; (iv) Practice and workflow redesign; and (v) Privacy and security resources. Each one of these core service areas mirrors what small, rural, and under-resourced providers need to be successful in exchanging public health information.

Overall, there are underfunded organizations that are trying to participate in public health data exchange. While there is a need to support small and less resourced organizations, any solution being required should not be cost prohibitive for any participant. Potential options include: (i) Tiered or waived fees for small and safety-net senders whose reporting is legally required; (ii) CDC-funded onboarding so the cost of connecting does not fall on the small sender; (iii) Short, standard, plain-language contracts; and (iv) Connect once, report many, so one connection satisfies several reporting duties.

Additional federal funding is necessary for CDC to provide necessary support to states, territories, and localities that use it to help support their communities and the organizations on the front lines of care delivery. CDC should also consider exploring cooperative agreements with CMS or the Health Resources and Services Administration for technology grants.

C–4: What funding and contracting approaches could CDC or other public-sector funders use to promote portability, competition, open standards, and sustainable market participation while avoiding unintended market distortion or vendor lock-in? (See also Section II.D for the broader governance section about this issue.)

WEDI Comment:

Contracts should provide for return or transfer of customer data, and, where appropriate, agreed mappings and configurations, in a documented interoperable format at contract end, with defined and reasonably compensated exit and transition support. Portability obligations should protect patient and customer data while preserving each party's rights in pre-existing or independently developed software, clinical content, guidelines, algorithms, documentation, and know-how; no transfer, sublicensing, or continued use of proprietary materials should be implied beyond the express license. CDC should promote applicable federally adopted standards and interoperability without limiting procurement to those standards alone where a use case requires complementary capabilities. CDC should fund connections to existing networks and avoid duplicative infrastructure.

D. Governance

D–1: What governance and accountability expectations should apply to data intermediaries, and should these vary based on the functions performed, the data handled, the entities/communities served, or the jurisdiction's laws and authorities?

WEDI Comment:

WEDI believes that data intermediaries, separate from the data sources they connect, should be subject to clear, consistent, and enforceable governance and accountability requirements that promote trust, protect the privacy and security of health information, and support reliable, interoperable data exchange. We note that TEFCA currently provides an important foundation for establishing these expectations. Building on this framework, CDC should consider establishing baseline requirements for data intermediaries, including operational procedures, organizational vetting, credential verification, independent third-party privacy and security accreditation, and ongoing monitoring and conformance testing, aligning any requirements with ONC's CEHRT requirements where possible.

Governance and accountability requirements should be based on the functions performed by an intermediary, the sensitivity and volume of data handled, and the organizations and communities served. Intermediaries that transform, link, or enrich data should have duties proportionate to the function they perform and their control over the process, including documenting material transformations and maintaining reasonable correction procedures for errors attributable to that process. These duties should not make an intermediary or technology vendor responsible for source data it did not create or control or require disclosure or transfer of proprietary methods or content. Sensitive data, such as substance use disorder records under 42 CFR Part 2, needs consent and segmentation controls. Requirements should account for applicable law while avoiding unnecessary duplication, conflicting obligations, and barriers to participation. CDC should also address liability concerns for transformation errors and PHI breaches at the intermediary.

WEDI encourages CDC to collaborate with applicable federal agencies, the RCE, and other impacted industry stakeholders to establish clear, coordinated expectations that support compliance while allowing flexibility to address different operational needs.

D–2: What safeguards would ensure transparent access to data intermediary services and prevent conflicts of interest, biased routing, vendor lock-in, proprietary dependencies, or market concentration—including across jurisdictions with differing legal requirements? (See also Section II.C for funding-specific mechanisms addressing the same risks.)

WEDI Comment:

WEDI believes safeguards for data intermediary services should address demonstrable risks through the operational framework. CDC should consider leveraging TEFCA and QHIN models, with improvements to review, onboarding, and monitoring. Safeguards should include: (i) Nondiscriminatory access for qualified participants under transparent, consistently applied

terms; (ii) Clear disclosure of applicable fees; (iii) Documentation of material routing criteria and safeguards against undisclosed preferential treatment; (iv) Disclosure and management of material conflicts of interest, including relevant affiliations; (v) Appropriate data portability and contractually defined exit rights that protect proprietary technology and content; and (vi) Multi-stakeholder input, including public health, providers, payers, and consumers. These safeguards should not impose a blanket prohibition on lawful affiliated offerings, integrated products, or separately licensed proprietary services.

D–3: What requirements should govern a data intermediary's authority to receive, access, route, transform, enrich, or disclose public health data, including delegated authority, reciprocal exchange, and compliance with jurisdiction-specific laws?

WEDI Comment:

The public health authority should delegate each function (receive, route, transform, disclose) in writing. HHS should also clarify, in guidance, when a business associate agreement is or is not needed for public health disclosures that pass through an intermediary. That uncertainty slows every onboarding today.

D–4: What roles should CDC, other federal agencies, state, tribal, local, and territorial (STLT) public health authorities, data intermediary governing bodies, participants, and other relevant entities play in oversight and accountability? How should these roles be coordinated, and what monitoring, audit, corrective-action, suspension, sanction, or termination mechanisms are appropriate?

WEDI Comment:

Due to the similarities between the public health data intermediaries and HIEs, CDC should consider working with CMS and ONC to establish a standing public-private advisory process building on previous coordinated activities from the Health IT Advisory Committee's Public Health Data Systems Task Force. In this continually changing health IT environment, it will be critical for the federal agencies to coordinate efforts and receive ongoing industry input from the entities directly impacted by these policies. Creating a public-private sector group convened under the Federal Advisory Committee Act (FACA) could assist in guiding and supporting the federal government as it furthers health IT and interoperability efforts and recommends additional automation opportunities.

Additionally, HIEs currently play a role in data exchange in regional communities providing a valuable solution for allowing patient information to flow from one provider to another in the care team, with the patient's consent. As we have stated, CDC could consider collaborating with other applicable federal agencies in exploring one option of establishing public health data intermediaries and HIEs as a utility that are managed at the state level or building on existing networks, per B-3.

E. Implementation

E-1: What tools, templates, or guidance (e.g., implementation playbooks, procurement language, data use/service- level agreement templates, security checklists, evaluation tools, governance models) do public health agencies need to evaluate, select, implement, and oversee data intermediary partnerships, and their associated outcomes?

WEDI Comment:

Public health agencies would benefit most from model procurement language, template data use and service-level agreements with state addenda, an intermediary selection guide, and an implementation playbook with test scripts and go-live criteria. WEDI workgroups develop similar industry guidance today and would welcome the chance to help draft and test these tools.

E–2: What barriers (e.g., workforce, funding, procurement, legal authority, governance, technical infrastructure, trust, sustainability, jurisdictional variation)—limit STLT public health agency readiness to use data intermediary services, and what support would address them? How should implementation build on existing investments and support coexistence, migration, or transition without unnecessarily replacing already functioning infrastructure? Where relevant, note differences by data intermediary type.

WEDI Comment:

With respect to data exchange standards, the use of a uniform standard is the key to decreasing barriers, burdens, and costs associated with health data exchange. As discussed in B-2, WEDI supports the use of a uniform standard for a specific data exchange need and believes the FHIR-based standards are a secure and scalable option for interoperable exchange of health information. Not all organizations have the capabilities to support high tech data exchange solutions.

Organizations conducting health data exchanges must understand the requirements and see value in any changes they must make to their current processes. Those that lack the necessary resources and technical expertise, such as small, rural, and under-resourced providers, may need financial support, technical support, or additional transition time. As discussed in C-3, CDC should look at the REC model as a means to provide additional support to these organizations at the regional level.

The largest STLT barriers are workforce, procurement cycles that outlast grant periods, and legal uncertainty about authority and HIPAA. CDC should state plainly that working direct feeds and HIE connections remain valid. Migration should happen only when it lowers cost or improves data, with parallel operation during transition. Payers and providers face the CMS prior authorization and interoperability API deadlines in January 2027, a possible HIPAA move to X12 version 008060, and attachment standards in May 2028, all drawing on the same technical staff. CDC should sequence its expectations so public health work does not compete with these deadlines.

Additionally, most providers rely on certified EHR functionality to conduct public health reporting. CDC should make every effort to align reporting requirements with EHR vendor release cycles or ONC certification timelines, as this is a practical constraint for large providers.

E–3: What approaches should CDC consider to test, learn from, and scale promising intermediary models or capabilities for public health purposes? How can pilots, demonstrations, learning collaboratives, phased implementation, or other approaches build evidence and trust while informing decisions about whether, when, and how to scale?

WEDI Comment:

WEDI has long supported pilots as an effective method of testing, evaluating, and scaling adoption of new technologies and requirements. The value of pilot testing goes well beyond simply proving that a standardized approach works as intended. Piloting a new standard or approach can identify workflow issues that will either need to be corrected by revising the standard itself or addressed by organizations during implementation. Successful piloting of a new standard and workflow approach can also serve to establish a clear ROI for participants, thus increasing support from the intended implementers and accelerating the adoption. For pilot testing to be truly successful, however, federal support is critical to establish the necessary framework for execution and incentivize pilot participants.

Pilots should also: (i) Run through several types of existing networks, such as a state HIE, health data utility, QHIN, and regional member-governed network; (ii) Set exit criteria up front for scaling, changing, or stopping; and (iii) Publish results, including failures. Low-cost testing events, such as HL7 Connectathons and WEDI forums, can test approaches before pilots begin. WEDI is happy to assist in helping to recruit pilot participants from our membership.

E–4: Where do public health needs and capabilities align with those of healthcare providers, payers, laboratories, community organizations, and other partners? What data, information, services, or capabilities could public health provide to partners (e.g., providers) through intermediaries to create shared value and strengthen reciprocal exchange? What collaboration approaches could enable this value, and what constraints, tensions, or tradeoffs should be considered?

WEDI Comment:

WEDI supports a “collect once, use many” approach where applicable law, the authority for disclosure, and the parties’ agreements permit the specified uses. Reuse should remain limited to authorized purposes, with appropriate safeguards and transparency; it should not create implied rights to use or disclose data, licensed clinical content, or proprietary materials for unrelated purposes. Sharing public health data with providers and health plans may create a stronger incentive to participate in exchange, where permitted. Data generated during a patient encounter can support multiple authorized use cases with less manual work and greater timeliness, including quality improvement, value-based payment, care coordination, and regulatory reporting.

Additionally, bi-directional public health data exchange between public health entities and providers is critical for a collaborative effort and increasing value. Providers and health plans want to participate in public health data exchange, but they want to receive data back from CDC, states, and localities with data relevant to the health of their communities. Providers and health plans receiving data back from public health entities, such as immunization histories at the point of care and for quality reporting; case and outbreak alerts for a provider's patients or region; and death data, which helps plans and providers keep records accurate, reinforces their importance in exchange processes, and increases the likelihood they will prioritize the health data exchange. Returning public health data to commercial entities requires clear, written purpose limits to keep public trust.

E–5: Where can CDC add the greatest value in strengthening the data intermediary ecosystem, and through what role(s)—for example, as a convener, funder, purchaser, technical assistance provider, standards advocate, evaluator, or facilitator of shared infrastructure? Where should CDC instead leverage, align with, or defer to existing public- and private-sector efforts?

WEDI Comment:

CDC can add value by establishing an ongoing public-private advisory process to ensure that public health agencies, health care organizations, HIEs, standards development organizations, and technology vendors have a meaningful role in shaping this critical area of data exchange. CDC can also work with appropriate agencies to leverage existing advisory bodies or establish and support a new FACA advisory group to guide data intermediary efforts, identify opportunities for administrative simplification and automation through standards, address privacy and security concerns, and address implementation challenges. CDC can also coordinate with its federal partners to align policy requirements, technical standards, implementation expectations, and compliance timelines to avoid duplicative mandates and parallel systems that increase burden for providers, payers, and public health agencies.

CDC should also consider building on existing infrastructure and regional capabilities rather than developing duplicative data exchange networks. Here, HIEs can play a pivotal role in strengthening the data intermediary ecosystem by facilitating trusted data exchange among providers, public health agencies, and other authorized participants. As we raised in our response to question D-4, one option to explore is for states to support HIEs as shared utilities, providing common capabilities and consistent expectations for interoperability, data exchange, and privacy and security while leveraging regional relationships and established infrastructure, or building on existing networks, per B-3. CDC can advance this approach through coordination, technical assistance, and support for scalable, standards-based solutions, while working with federal agencies, states, and private-sector partners to build on existing efforts and address gaps where federal leadership can have the greatest impact.

F. Dynamic Evaluation

F–1: Where can CDC add the greatest value as an evaluator (e.g., in providing guidance on evaluating pilots or implementation models, synthesizing evaluation evidence across

settings, or evaluating the strategic outcomes and value of the broader intermediary framework)?

WEDI Comment:

As discussed in E-3, WEDI has long supported pilots in their effectiveness of testing, evaluating, and scaling implementations of new technologies and requirements. CDC's support and use of pilots will serve the role as an "evaluator" of this work. Individual pilots cannot show which models work where. CDC can, if every site reports the same small set of core measures. CDC should publish that measure set, gather results, and report them openly at least once a year.

This is, again, another opportunity for CDC to collaborate with its federal partners on current implementation programs and resources and establish a shared approach to a pilot testing framework. The value of pilot testing cannot be overstated in the benefits it brings to impacted organizations and other participants within the data exchange ecosystem. Federal support for these pilots is critical to establishing the necessary structure and resources for execution.

F–2: What frameworks, benchmarks, and measures should CDC use to evaluate the intermediary framework, including impacts on workflows, workforce burden, user experience, data usability, situational awareness, and response capacity? What data sources and methods could support feasible measurement and assess the contribution of intermediary-enabled exchange to observed changes and, where feasible, support causal attribution?

WEDI Comment:

Core measures could include: (i) Time from clinical event to receipt by public health; (ii) Share of required data elements populated and valid; (iii) Share of required reporters connected, including rural and small; (iv) Days to onboard a new sender; (v) Staff hours and cost per sender; and (vi) Number of public health uses served by one connection. Most can come from intermediary logs. Phased rollouts give natural comparison groups for attribution.

As discussed in E-3, a pilot test could require testing all aspects of the process being implemented, not just the technical or system changes. Impacts on workflows, workforce burden, user experience, data usability, situational awareness, and response capacity are critical elements that should be evaluated in a pilot. Results of the pilot could demonstrate to users the value and expected ROI from the changes, which can speed the adoption rate and scaling of solutions. Additionally, these pilots should be conducted in a fully transparent manner with the results made public.

F–3: How should CDC and STLT public health partners assess value and cost efficiency, including startup and recurring costs, costs borne by different parties, avoided costs, and monetary and non-monetary benefits to public health, healthcare, and other ecosystem participants? How should VerDate Sep2014 17:21 Sep 18, 2026 Jkt 268001 PO 00000 Frm 00023 Fmt 4703 Sfmt 4703 E:\FR\FM\21SEN1.SGM 21SEN1 59780 Federal Register/Vol. 91, No. 181/Monday, September 21, 2026/Notices evaluation account for the distribution of costs and benefits and unintended consequences such as added burden,

cost shifting, reduced flexibility, inequitable distribution of benefits, or vendor dependency?

WEDI Comment:

Providers, laboratories, and payers bear much of the cost of public health reporting. An evaluation that counts only public health spending will overstate value. CDC should: (i) Count costs on the health care side; (ii) Count avoided costs, such as retired point-to-point interfaces; (iii) Watch for cost shifting onto network participants; and (iv) Report who paid and who benefited by participant type.

Conclusion

WEDI appreciates CDC's efforts to solicit public feedback on its work to strengthen health data exchange and how data intermediaries can support secure, scalable, standards-based public health data exchange in support of improving the nation's public health systems. We would welcome the opportunity to convene our members, including health plans, providers, clearinghouses, networks, and vendors, to give CDC structured feedback as the framework develops, and to help draft the implementation tools described above. We hope our comments will serve to assist you as you move forward with your work. Please contact Robert Tennant, WEDI Executive Director, at rtennant@WEDI.org with any questions on these comments and recommendations.

Sincerely,
/s/
Merri-Lee Stine
Chair, WEDI

cc: WEDI Board of Directors