DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket CDC–2026–1519]

Data Intermediaries and Approaches To Strengthen Public Health Data Exchange

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) seeks broad public input on how data intermediaries can be used to support secure, scalable, standards-based public health data exchange. CDC invites public comment to inform the evaluation and to explore how data intermediaries can advance broader goals to prevent disease, detect emerging threats, drive state-of-the-art solutions that empower communities, and strengthen public health systems for a safer, healthier nation.

DATES: To be assured consideration, written or electronic comments must be received on or before November 20, 2026.

ADDRESSES: You may submit comments, identified by docket number CDC–2026–1519, by any of the following methods. Please do not submit comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Attention: Request for Information: Office of Public Health Data, Surveillance, and Technology, Centers for Disease Control and Prevention. 1600 Clifton Rd. NE, MS H21–8, Atlanta, GA 30329

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Abigail Viall, Acting Lead, Technology Implementation Office Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, GA 30329. Phone: 1–800–232–4636. Email: *OPHDSTPolicy@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose/Introduction

The ability to prevent disease, detect threats, and respond effectively to public health events, including public health emergencies, depends on timely, accurate, and actionable data flowing across a complex ecosystem of patients, healthcare providers, public health agencies, and communities. Without data, public health professionals cannot see patterns, identify risks, or inform and evaluate interventions. With high-quality, well-connected data, public health practitioners are better able to act with speed and precision. Increasingly, public health action depends not only on access to data, but also on the ability to integrate, interpret, and apply those data across multiple levels—from the individual case to the community to the larger population level.

Over the past several years, public health has made meaningful progress in strengthening its connection to the broader health information technology (health IT) ecosystem. CDC's data modernization investments have improved the ability of public health agencies to access and use electronic health data. Public health programs now routinely leverage electronic laboratory reporting, electronic case reporting, and other digital data streams to support surveillance and response. CDC has adopted an agency-wide data modernization approach through the Public Health Data Strategy (*http://www.cdc.gov/Ph.D.s*). Through the development of the One CDC Data Platform (1CDP) (*https://www.cdc.gov/data-modernization/php/one-cdc-data-platform*), the agency is creating a unified data platform to support CDC's everyday work as well as public health emergency response.

Despite this progress, data inconsistency, siloing, and interoperability challenges across systems continue to limit public health's ability to respond swiftly to both chronic and emerging threats. Addressing these challenges will require approaches that build on existing investments to make data more accessible, standardized, and usable across all levels of public health. Data intermediaries—trusted organization, network, platform, or governed service that enables secure, standards-based exchange and stewardship of health-related data—have long supported critical aspects of data exchange among public health agencies and between public health and healthcare (see Section II.A. for a comprehensive definition). However, the evolving health IT ecosystem presents new opportunities to consider how a range of intermediary models and capabilities can more effectively support public health data needs while also delivering value to healthcare. The continued evolution of health information exchanges (HIEs), including the emergence of health data utilities (HDUs), alongside broader developments such as the Trusted Exchange Framework and Common Agreement (TEFCA) and the Centers for Medicare & Medicaid Services (CMS) Digital Health Tech Ecosystem, provides an opportunity to examine how intermediaries can collectively enable more seamless, timely, and scalable data exchange, and move the ecosystem beyond technical interoperability toward greater data liquidity.

Given these developments, CDC is evaluating how data intermediaries can be used to support secure, scalable, standards-based public health data exchange, while protecting privacy.

II. Solicitation of Public Comments

CDC is evaluating how data intermediaries can support secure, scalable, standards-based public health data exchange. CDC invites public comment to inform that evaluation and to explore how data intermediaries can advance broader goals to prevent disease, detect emerging threats, drive state-of-the-art solutions that empower communities, and strengthen public health systems for a safer, healthier nation.

We encourage interested parties to respond to as many of the questions below as possible. The questions are intended to solicit input from multiple individuals and groups. To support CDC's review of responses, please prioritize clarity and conciseness and identify the applicable question label(s) (for example, XX–1).

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email.

A. Definition of Public Health Data Intermediary

For the purposes of this RFI, CDC defines a public health data intermediary (data intermediary) as a trusted organization, network, platform, or governed service that enables secure, standards-based exchange and stewardship of health-related data among data sources and public health authorities by providing shared technical, operational, and governance capabilities that seek to reduce connectivity burden and improve the quality, timeliness, and usefulness of data for public health practice, while protecting individual privacy and confidentiality. Data intermediaries may provide additional services such as analytics, visualization, technical assistance, and community engagement to make data actionable for public health.

Data intermediaries can be centralized or decentralized; operate at local, regional, state, territorial, tribal, or national scale; and receive data from diverse sources, including healthcare providers, payers, laboratories, pharmacies, non-traditional testing and reporting sites (*e.g.,* schools and pop-up clinics), and federal contributors and platforms. Data intermediaries that already do or potentially could support public health include HIEs, HDUs, TEFCA, Qualified Health Information Networks (QHINs), CMS-Aligned Networks, Health Center Controlled Networks (HCCNs), public health data hubs and exchange platforms, or other entities that provide shared technical, operational, governance, or analytic capabilities for public health purposes.

Question II.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?

B. Standards and Technical Capabilities

Data intermediaries vary in function, technical capability, use of standards, and maturity. CDC is developing a Public Health Intermediary Framework to help public health organizations specify, select, and evaluate intermediary capabilities while allowing for different architectures, services, and public health use cases. For purposes of this RFI, CDC is considering a layered framework consisting of the following:

- *Universal intermediary baseline:* Core capabilities, safeguards, and practices applicable to any intermediary serving public health.
- *Service-specific profiles:* Additional expectations based on services provided, such as routing, aggregation, transformation, record linkage, terminology management, analytics, or workflow orchestration.
- *Public health use-case profiles:* Additional expectations based on specific public health programs, data streams, or workflows, such as electronic case reporting, electronic laboratory reporting, immunization data exchange, syndromic surveillance, or emergency response.

Expectations may also vary by maturity level, from minimum participation requirements to more advanced operational capabilities. This section seeks input on the technical and operational capabilities, standards, maturity, and performance expectations that should inform the framework; Section II.D addresses governance considerations.

Question II.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*).

Question II.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.

Question II.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?

Question II.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?

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

C. Shared Infrastructure: Funding and Sustainability

Shared data intermediary infrastructure has the potential to increase data liquidity and accelerate timely public health action, but its sustainability requires funding that extends beyond initial implementation to cover ongoing operations, maintenance, governance, security, and scalability. CDC seeks input on sustainable funding approaches and the allocation of financial responsibility for shared infrastructure.

Question II.C–1: What funding and revenue sources do data intermediaries currently rely on to support public health services, which entities bear those costs, and which entities receive the resulting benefits? How does this vary between public health-specific services and shared infrastructure supporting multiple participants or purposes (*e.g.,* healthcare delivery)?

Question II.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.

Question II.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.

Question II.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.)

D. Governance

CDC is seeking input on the governance framework needed to support effective use of data intermediaries, covering accountability, neutrality, authority, oversight, and equitable implementation. As in Section II.B, CDC is applying a layered approach—a universal governance baseline, service-specific governance profiles, and use-case/jurisdictional governance profiles—so that requirements scale appropriately with the functions an intermediary performs and the laws that apply to it.

Respondents should consider how governance expectations address roles and delegated authority, participant obligations, permitted and prohibited uses, audit and oversight rights, dispute resolution, corrective action, continuity, and reliance on downstream entities.

Question II.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?

Question II.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.)

Question II.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?

Question II.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?

Question II.D–5: How should governance accommodate jurisdictional differences in law, reporting mandates, privacy, consent, data use agreements, and public health authority while minimizing administrative, technical, and financial burden and supporting equitable participation?

E. Implementation

CDC seeks input on the practical assistance, readiness conditions, partnerships, and learning approaches needed to integrate intermediaries into public health data modernization. Because needs vary across settings, respondents should provide relevant context, such as jurisdiction or data intermediary type, organization size, technical maturity, primary use cases, and material timing or resource constraints.

Question II.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?

Question II.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.

Question II.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?

Question II.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?

Question II.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?

F. Dynamic Evaluation

CDC seeks input on how to evaluate the outcomes, value, and cost efficiency of its intermediary framework over time. This section focuses on CDC's framework-level strategic impact and learning rather than the intermediary capability and performance measures addressed in Section II.B. or implementation, partnership, and oversight addressed in Section II.E. Evidence generated at the intermediary and implementation levels may inform this broader evaluation. Evaluation should be feasible, minimize reporting burden, account for context and unintended consequences, and inform decisions to sustain, modify, expand, replace, or discontinue approaches, and used to refine the intermediary framework.

Question II.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)?

Question II.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?

Question II.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

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?

(Authority: 42 U.S.C. 241 and 42 U.S.C. 247d–4)

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3400]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by October 21, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs—21 CFR Part 316

OMB Control Number 0910–0167—Extension

This information collection helps support implementation of sections 525, 526, 527, and 528 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360aa, 360bb, 360cc, and 360dd), as well as related guidance and Agency forms. Sections 525, 526, 527, and 528 of the FD&C Act pertain to the development of drugs for rare diseases or conditions, including biological products and antibiotics, otherwise known or referred to as ''orphan drugs.'' Specifically, section 525 of the FD&C Act requires written recommendations on studies required for approval of a marketing application for a drug for a rare disease or condition. Section 526 of the FD&C Act provides for designation of drugs as orphan drugs when certain conditions are met; section 527 provides conditions under which a sponsor of an approved orphan drug enjoys exclusive FDA marketing approval for that drug for the orphan indication for a period of 7 years; and, finally, section 528 is intended to encourage sponsors to make investigational orphan drugs available for treatment of persons in need on an open protocol basis before the drug has been approved for general marketing. Open protocols may permit patients who are not part of the formal clinical investigation to obtain treatment where adequate supplies exist and no alternative effective therapy is available.

Agency regulations in part 316, subpart A (21 CFR part 316, subpart A) (§§ 316.1 through 316.4) identify the scope of coverage, applicable definitions, and statutory provisions applicable to orphan drugs. The regulations in part 316, subpart B (§§ 316.10 through 316.14) set forth content and format elements for written recommendation requests and discuss FDA providing or refusing to provide the requested written recommendations. Similarly, regulations in part 316, subpart C (§§ 316.20 through 316.30) prescribe content and format elements for requesting orphan drug designation; identify submission schedules for requisite information including amendments, updates, and reports; and provide for publication and revocation of orphan drug designation. Regulations in part 316, subparts D and E (§§ 316.31 through 316.40) address orphan drug exclusive approval and open protocols for investigations, respectively. Finally, regulations in part 316, subpart F (§§ 316.50 through 316.52) provide for the issuance of guidance documents that apply to the orphan drug provisions of the FD&C Act and regulations in part 316. The list is maintained on the internet and guidance documents are issued in accordance with our good guidance practices regulation in 21 CFR 10.115, which provide for public comment at any time.

The information collection includes the Agency guidance document entitled ''Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff'' (July 2015), available for download at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-office-orphan-products-development.* It provides recommendations to industry, researchers, patient groups, and other stakeholders interested in requesting a meeting, including a teleconference, with the Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. It is also intended to assist OOPD staff in addressing such meeting requests. The guidance describes procedures for requesting, preparing, scheduling, conducting, and documenting such meetings and discusses background information we recommend be included in such requests.

The information collection includes Form FDA 4035, FDA Orphan Drug Designation Request Form, intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from FDA. The form is a simplified method for sponsors to provide only the information required by § 316.20 for FDA decision making. Orphan drug designation requests and related submissions (amendments, annual reports, etc.), humanitarian use device designation, and rare pediatric disease designation requests and submissions may be submitted electronically by email to the OOPD.

As communicated on our website at *https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products,* respondents may submit orphan drug designation requests electronically through the Center for Drug Evaluation and Research (CDER) NextGen portal, or by emailing the required information to *orphan@fda.hhs.gov;* or by mailing the required information to the OOPD at the address