

National Headquarters
2231 Crystal Drive, Suite 450
Arlington, VA 22202
(202) 371-9090

Regional Office
600 Peachtree Street NE, Suite 1000
Atlanta, GA 30308
(202) 371-9090

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June 17, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement Draft 2

Dear Dr. Rucker:

The Association of State and Territorial Health Officials (ASTHO) appreciates the opportunity to submit comments regarding the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*. ASTHO looks forward to working with the Office of the National Coordinator for Health Information Technology (ONC) as it seeks to finalize TEFCA, including any related standards, processes, rules, or funding opportunities.

ASTHO is the national nonprofit organization representing the state and territorial public health agencies (S/THAs) of the United States, the U.S. Territories, and the District of Columbia. ASTHO's members, the chief health officials of S/THAs, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice. S/THAs play a critical part in improving population health in their states—they assess community needs; design, implement, and evaluate programs that prevent or mitigate disease or injury; work to reduce health disparities; identify best practices in public health and evaluate their impacts; and convene and collaborate with stakeholders and communities. In addition, state and territorial health officials (S/THOs) have wide-ranging responsibilities and relationships with their state Medicaid agencies, ranging from statutory oversight, membership in an umbrella agency, or reporting separately to the governor or other state or territorial executive.¹ Thus, S/THAs have a unique role in coalitions, partnerships, and activities that improve population health.

S/THOs advance population health and adapt strategies to combat the evolving and leading causes of illness and poor health outcomes by utilizing informatics and multiple data sources to inform decisions. They develop an increasingly integrated health system by partnering with public health and healthcare organizations and collaborating with diverse stakeholders and community leaders. Partnerships with stakeholders are essential to exchanging information and developing programs that address community

¹ In five states (Kansas, Maryland, Montana, New York, and Utah), the S/THO has statutory oversight of Medicaid). In 14 states, the S/THA and Medicaid are part of an umbrella agency. In 31 states and Washington, D.C., the S/THA and Medicaid report separately to the governor (or, in Washington, D.C., to the mayor).

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needs and align programs or activities to reduce duplication or misalignment. Furthermore, partnering and exchanging information with sectors outside of health will be essential as greater recognition for collecting data relative to the social determinants of health expands. Data partnerships, sharing, and exchange between public health, healthcare and community-based organizations has become increasingly common and critical to public health practice. Public health agencies have programs that receive and send data to clinical partners through their health IT systems. Public health agencies also strive to make data transactions with clinical partners as seamless as possible by adopting interoperability standards set forth by ONC.

Comments

General

ASTHO affiliates and partner organizations understand TEFCA to be a voluntary framework for supporting information exchange and caution against issuing future rules that would require compliance, particularly from a subset of the health IT developer community. We do not recommend singling out this community as mandatory participants. Additionally, we note that requirements that fall on vendors contracted to operate public health registries may incur costs that public health is not prepared to absorb.

We encourage ONC to support a single on-ramp to interconnected health data networks, enabling health care providers to exchange information with S/THAs to support public and population health surveillance and provide other essential public health services. We believe that TEFCA's nationwide connectivity will (1) enable patients' electronic health information (EHI) to be available when and where it is needed, with the goal of supporting nationwide scalability. Furthermore, we recommend that ONC involve S/THAs in the development of policies and standards for public health programs and suggest that ONC work with S/THAs to ensure that *QHIN Message Delivery* "push," *QHIN Targeted Query* "pull," and *QHIN Broadcast Query* messages as described in the TEFCA Draft 2 support public health's needs. ASTHO advocates for the single "on-ramp" push method in a Direct Health Information Network to allow Public Health to accomplish its purpose in population health surveillance. The ONC Interoperability Standards Advisory (ISA) has been supportive of addressing needs on Meaningful Use/Promoting Interoperability standards. The US Core Data for Interoperability (USCDI) Taskforce, however, currently lacks public health representation; therefore, we recommend a consensus-based standard process that includes S/THAs and provides an opportunity for public health to provide input on decisions regarding USCDI.

TEFCA's proposed inter-network connectivity and single on-ramp can support these electronic exchanges, including state and federal mandated reporting of diseases as more providers become connected to the network, now that electronic health records are increasingly available as a source of data. The value of TEFCA to public health depends on the trust and technical components of the framework to support disease reporting, surveillance, and other public health activities through 'push' transactions. Therefore, we strongly appreciate ONC's inclusion of 'push' data exchange transactions in the second TEFCA draft.

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Public health is a government-organized and population-focused activity that has different legal bases and needs from patients or providers. However, there are some instances of public health data exchange transactions that aren't accounted for in the second draft (e.g., public health registries that contract vendors to manage their registry). As such, ONC should take additional steps to engage, convene, and provide opportunities for S/THAs to contribute to the development of the final framework and agreement, the development of terms and conditions for Qualified Health Information Networks (QHINs) that abide by the common agreement, and a pathway to advise or be represented within the governance of the recognized coordinating entity (RCE) to ensure that public health needs are met in the common agreement, including additional required terms and conditions (ARTCs), and in any other supporting contracts and standards.

Definitions

Public Health

We appreciate that TEFCA Draft 2 references the permitted disclosures that HIPAA Privacy Rules allow to health oversight entities in describing public health data exchange purposes. We also recommend that public health be permitted Use and/or Disclosure as outlined under other Applicable state Laws that speak to data exchange for public health activities and purposes. Public health should also be recognized differently from the data exchange needs and activities of patients and providers and should not be held to the same considerations. Public health agencies should also not be held to the same requirements that covered entities or business associates have as it relates to patient consent or authorizations and charges for responding to queries from public health. Public health agencies use and aggregate large volumes of data to advance disease surveillance efforts for disease control, prevention, and policy analysis. Furthermore, public health agencies may also need to access and use patient information for case management, care coordination, and in supporting clinical decision support so providers can make informed treatment decisions (e.g., managing disease outbreaks, recommending immunizations and/or vaccines). ASTHO recommend that ONC recognize and support the full spectrum of public health data exchange activities within TEFCA, including any related standards, processes, rules, or funding opportunities; and that any relevant charges be driven by public health versus an external party.

HIPAA also explicitly permits international access to health data, when done in conjunction with a public health agency. TEFCA Draft 2's exclusion of international exchange should not apply to public health activities requiring data exchange.

Electronic Health Information

We recommend reconciling the definition of electronic health information (EHI) and other currently used terms (e.g., personal health information), to what has been included in the ONC proposed rules for interoperability and the U.S. Core Data for Interoperability (USCDI). EHI can be regarded as electronic information that identifies an individual/patient's past, present, or future health status or condition, and is a collection of their entire medical and behavioral history in electronic form.

Individual Access Services

ASTHO appreciates the goal of ensuring patients have access to their own data. That said public health has not been provided with adequate resources to ensure it could respond through a QHIN to an

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individual's access service request (provide an automated response to a smart phone application). Public health agencies are not covered entities or business associates under HIPAA and should not be treated as such. Some public health laws and rules do not allow individuals to access their own data or restrict how access is obtained (Example: a state rule requires the patient to come in person with photo ID for identity proofing). Furthermore, there may be other constraints, such as whether a non-custodial parent is authorized to access a minor's health data, or an individual is under a conservatorship, that requires additional effort in ensuring the requester is properly authorized to receive data. We encourage ONC to consider providing public health agencies a specific exemption from this requirement as HIPAA does. A suggestion is to update language to extend the exemption provided to federal agencies to also include S/THAs and that these agencies be able to respond to individual requests only when laws allow and via methods, they have resources for.

While this section says that applicable laws can allow disclosure of information despite someone exercising the right to not disclose, we would like to see clarity for public health reporting. If there was any lack of clarity this would be detrimental to public health agencies' core mandates to prevent and control diseases and would put the population of every state at risk. Public health agencies have mandated core responsibilities and specific provisions under HIPAA as a "health oversight agency", which allows them to collect data without patient consent or authorization. This must be echoed and supported in TEFCAs more clearly. While TEFCAs say that applicable laws can allow disclosure of information despite someone exercising a "Meaningful Choice" decision to not disclose, more specific language should be added to indicate that QHINs, participants, and participant members need to consider state laws from the beginning as "Meaningful Choice" implementation approaches are advanced. Additionally, if a QHIN or other participant is registering a patient's "Meaningful Choice" and there is actually an option not to report that data to public health (such as a voluntary immunization registry), public health needs to be notified of the patient's choice, consistent with applicable law.

Relationship to HIPAA vs. State Laws (pages 16, 18-19, 46)

Public health agencies are specifically listed as health oversight agencies under HIPAA and are permitted to receive and transmit patient data without consent. We request specification that the minimum necessary requirements from HIPAA will not apply to public health agencies participating in a QHIN and that the public health ability to receive and transmit patient data without consent will continue in TEFCAs.

It should also be made clear in TEFCAs, for example, that the provisions for individual access services do not always apply to public health registries. Public health should be able to declare whether any particular system may support access. Specific language in TEFCAs that releases federal agencies from HIPAA should be extended to include state agencies as well, based on the same bases such as sovereign immunity and other applicable law.

A federal or state agency that is serving as a Participant and is not otherwise subject to the HIPAA Rules is not required to comply with the HIPAA Privacy and Security Rules referenced in these MRTCs. The federal or state agency will comply with all privacy and security requirements imposed by applicable state and federal laws.

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What is more, TECCA exchange, more than just not violating state (and federal) laws, should explicitly require that “Participants,” “Participant Members,” and QHINs should comply with, and support, state laws. Public health needs stronger incentives and support to ensure that state laws are complied with in an ongoing way and federal regulations should continue to support such compliance.

QHIN

Public health has many registries that have laws mandating reporting. Having a “push” based query added to the exchange framework is important to help clinical partners meet these mandates to submit data automatically when an appropriate code indicates the condition is notifiable. Public health agrees that having a push-based query will be beneficial to reporting. The automatic request for information and transfer will be beneficial for gaining access to information that would be used to develop Public Health policies. However, we ask that there be further explanation and clarification on QHIN Message Delivery and its intended purpose. In TECCA, when it states that QHIN ensures that messages are delivered to the patient or individual it is sent to, who or what ensures that the message is being delivered, and what are his/her/its role and responsibilities?

There are concerns that providers will rely on QHINs for public health reporting, which would result in extra costs and burden to public health agencies to find an alternative route. We would like ONC to engage S/THAs in discussing these concerns and alternatives.

- **Fees (page 20):** Given the importance of public health reporting, and its requirement in state or federal law, we do not support the removal of the provision in TECCA Draft 1 that did not allow a QHIN to charge for response to public health data exchanges. The provision in TECCA Draft 1 should be reinstated to ensure there is no charge to public health queries or establish a different fee structure that does not impact the incentive to input or query public health data. This is critical to support the ongoing population health work of public health, protect our ability to receive standards-based health IT messages of disease case reporting (e.g., electronic case reporting, public health registries, electronic laboratory reporting) as well as responses to queries regarding non-notifiable conditions such as federated queries regarding hypertension and diabetes and other non-notifiable conditions such as neonatal abstinence syndrome. We are concerned that fees, even if reasonable by HIT standards, would quickly become onerous and decrease the data exchange on which modern S/THAs depend on. In a change from the first draft of TECCA, public health is no longer excluded from paying for QHIN transactions. Public health cannot, and should not, be expected to pay charges for QHIN data exchanges made in support of state laws. These charges would be above and beyond the health information network membership charges for public health agencies that are already difficult for public to support. The new charges would, among other things, obstruct public health agencies from using data for surveillance work to address disease control, handle emergency response, and develop public policy.

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- **QHIN Technical Framework:** The framework relies almost completely on Integrating the Healthcare Enterprise (IHE) standards and transactions which do not represent most health information exchange implementations today. Most public health transactions (immunizations for example) are not currently implemented with IHE technologies. This framework may make it difficult to ensure public health transactions can be easily sent between two QHINs and would suggest that standards-based implementations in use today such as HL7 standards be supported. Another concern is if only IHE standards are used between QHINs that implies that they must unencrypt the message to translate it into another standard for transmission. We recommend that QHINs be required to follow national standards set by ONC and included in the ISA. The QHIN Technical Framework (QTF) should also separate transport and payload standards for “push” exchange. The specific standards used for QHIN to QHIN “push” transport could be executed in several different ways, but TEFCA should insist that for any of them a variety of payloads are allowed (HL7 v2, CDA, and FHIR bundles) and that the “header” information of each of these payloads is kept intact and unaltered through the TEFCA described multi-hop process. HL7 FHIR API standards as specified in the QTF do not adequately support “push” messaging through a decision support intermediary because it does not specify a messaging header. “FHIR Messaging” needs to be specified in addition to the basic FHIR API to support the “push” use through decision support intermediaries.
- **QHIN Delivery ‘Push’ Transactions:** Public health has many registries that have laws in place mandating reporting. “Push” data exchange is important to public health, but it is also important to many healthcare and patient’s data exchange needs as well, especially for healthcare providers to meet mandates to submit data automatically when an appropriate code indicates the condition is notifiable. The definition of the QHIN Message Delivery seems mostly adequate except that it is defined too vaguely about whether a receiving QHIN must ensure the message gets delivered to the participant or individual it is required to be sent to. It states that there is no obligation to further transmit it which is not clear. It should be clear that if a QHIN gets a push request it should ensure delivery within its network to the requestor or ensure it goes to the QHIN where the requestor is a member. The genesis of Direct and DirectTrust speaks to the importance of “push” in health information exchange and makes a compelling case for including this health information network in the same trust fabric and single on-ramp as the rest of health information exchanges in TEFCA. Direct needs a more robust trust framework to eliminate point-to-point data use agreements and TEFCA needs Direct to ensure the single on-ramp that is a critical component of the TEFCA.
- **Business Associate and Operations Authorities:** Aside from Direct, the largest health information networks have moved to advancing strong trust frameworks. Both the eHealth Exchange and CommonWell now manifest HIPAA Business Associate authorities across their participants. Important public health activities like electronic case reporting (eCR) and electronic laboratory reporting (ELR) make use of common services platforms that use Business Associate

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and operations authorities to ease clinical – public health interoperability. TEFCAs should extend its trust framework such that HIPAA Business Associate authorities and operational needs can be supported as well.

Recognized Coordinating Entity

ASTHO supports the need for the inclusion of a section in TEFCAs that addresses and clarifies how the Recognized Coordinating Entity (RCE) will handle issues when an approved QHIN is found to be in violation of any required TEFCAs components. It is crucial that TEFCAs discuss how the RCE will ensure privacy, security, and accountability of the QHINs. ASTHO suggests that the role of an RCE in this situation be defined as:

- Develop a Common Agreement that includes the MRTCs and ARTCs for ONC approval and publication to HealthIT.gov and the Federal Register.
- Convene public listening sessions to share and discuss common violations of TEFCAs by QHINs.
- Identify and monitor voluntary QHINs.
- Implement an ONC-approved process to adjudicate QHIN noncompliance with the Common Agreement.
- Implement a process that will update the Common Agreement when needed.
- Modify/update QHIN Technical Framework.
- Propose strategies that an RCE could employ to sustain the Common Agreement.
- Discuss and develop a common language for technical guidance on variations in QHIN.
- Assess the readiness of the industry to implement ONC standards.

Some functional and technical considerations need to be standardized and applied to the participants and participant members that are “behind” QHINs. An example is the consideration for how frequently QHIN data caches will be refreshed to deliver current, up-to-date, query-response data. QHINs should also not completely independently “specify the format and content of acceptable Message Delivery Solicitations.” There should be shared standards for this to be fully functional for “push.” ONC will not be able to, and should not, tease out these issues, but the RCE should be enabled to develop them as it moves forward with its activities.

Relationship of RCE to QHIN

To carry out the roles of an RCE, we agree that an entity must first comply with the requirements to become a QHIN and determine the type of relationship a QHIN applicant could have with an RCE who approves them. It is important that the RCE remain unbiased in its review and approval process.

What qualifies as a QHIN:

- Must be a Health Information Network (HINs) that satisfy all the conditions of the Common Agreement and accompanying QTF:
 - Utilization of Connectivity Services for sending and receiving EHI.

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- Responding to requests for EHI for all Exchange Purposes described in the Common Agreement.
- Adhere to all Privacy and Security requirements.

The possible relationships between an RCE and QHIN applicant are:

- Participant – A person or entity that have entered into a contract to participate in a QHIN. The participant may include persons/entities that use the services for a participant to send and receive EHI.
Examples: HIN, health system, Health IT developer, Payer, or Federal Agency, HIEs, Health Care Organizations, Managers.
- Individual User – May have a Direct Relationship with QHIN, Participant, or Participant Member depending on the structure of the QHIN to which they belong to.
- Direct Relationship – A Direct Relationship is the only/most common relationship between RCE and QHIN applicant. A Direct Relationship will require QHINs to deal with many layers of participants (listed above) which will be a burden on QHINs. ASTHO and Washington State want to at least warn RCE about the implications of a Direct Relationship.

Exchange Modalities

QTF focuses on technical and functional requirements for interoperability among QHINs (i.e. standards to enable QHIN-to-QHIN exchange). ASTHO agrees that all three modes (QHIN Broadcast Query, QHIN Directed/Targeted Query, and QHIN Message Delivery 'Push') allow for patient information to be exchanged at a population level.

We appreciate the challenges the industry currently has with maturing the use case of population-level data exchange, but also see real benefit in this exchange to further population health outcomes, including social determinants of health. It's important to support standards and consistent definitions rather than the situation we have now where many different definitions are used for different aspects of population health, often poorly defined, and most frequently incompatible and incomparable to other definitions. Strong leadership displayed by including this measure in the original proposal should be lauded, encouraged, and supported. By using aggregators like HIEs a public health agency can more efficiently do population health work and could use the TEFCA framework to share data with other states. TEFCA Draft 2 should recognize that public health agencies can leverage the Clinical Data Repository within their state or territory's HIE to allow for analytics to be done for chronic disease surveillance. Rather than relying on data to be submitted to public health agencies, they can put an analytic platform on the HIE repository and automate this work. We ask that consideration be made to insert this exchange back into TEFCA or at least put in pieces that will advance the maturity of this exchange within the industry.

Standards Development for Population Health

ASTHO also requests that ONC explicitly engage S/THAs when selecting and developing new standards. We recommend that ONC develop a standards version advancement process with a more collaborative method for determining when standards are ready for implementation across organizational boundaries

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when there are two or more partners (including S/THAs) involved in the exchange. It is critical that one or more partners in the exchange not be able to implement new versions of interoperability standards that S/THAs and other trading partners are not yet prepared to support. In addition, we recommend that data exchange systems that adopt new versions retain support for previous versions, so as not to disrupt existing interoperability.

The “standards hierarchy” ONC defines of “*Adhere to applicable standards for EHI and interoperability that have been adopted by the U.S. Department of Health & Human Services (HHS), approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA)*”, needs to be reconsidered. Part of the reason for having an RCE, for separating the QTF standards, and for abiding by the National Technology Transfer and Advancement Act (NTTAA) is to avoid individual program and government choices that don’t always represent broad community participation like consensus-based standards development processes do. The approach to standards specification identified in TEFCA, draft 2 does not ensure public health participation going forward. This can easily result in the framework not supporting critical messaging and necessitate continued operation of alternate exchange tools.

Real World Testing

In coordination with public health organizations and agencies, we support ONC’s development of a directory of S/THAs that can be available to support real world testing of public health data exchange transactions and clinical care to public health data exchange transactions. If adopted, there is an opportunity for S/THAs and other organizations (e.g., Certified Electronic Health Record Transfer vendors) to collaborate, ensure more consistent national implementation, and potentially save costs by cost sharing between stakeholders (e.g., public health, healthcare providers, and other organizations involved) and using a common infrastructure that would be developed and deployed to support such testing.

Lab reporting

ASTHO encourages ONC to specifically outline how lab reporting will be impacted by and/or interact with the exchange framework. Is lab reporting assumed to be a participating member much like immunization registries?

Interstate Data sharing

Public health agencies face challenges in sharing data across state lines with other public health agencies and/or with other partner agencies and stakeholders. We support engaging S/THAs to develop clearer language for TEFCA that would address this need and define how the framework would interact with areas (i.e., lab reporting, AIMS platform) where public health does have an interstate hub.

Patient Matching/Identity Resolution

We recommend patient matching as a critical tool for promoting improved patient safety, better care coordination, advanced interoperability, and improved public health surveillance in order to avoid information duplication or erroneous data. We encourage ONC to take an active role in standardizing operations and guidance for implementing master person indexing, with S/THA collaboration and

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involvement, to ensure interoperability between public health, insurance companies, and clinical providers. If TEFCA cannot at this time address patient matching, we encourage the RCE to establish standards for QHINs to follow. This is critical in protecting patient safety. As messages transition between QHINs, it is possible for multiple patient-matching activities to occur. If these are not managed carefully, there may be false matches between the origin and destination data points.

The 6 Principles

ASTHO supports the layout of these principles to guide TEFCA, including the call to adhere to standards in the ONC Interoperability Standards Advisory (ISA) and making terms/conditions/contractual agreements public while adhering to security and privacy standards. Security and privacy need to be further determined after appropriate engagement with the contracting parties to define what will be included and excluded (e.g., IP addresses, communications, network connectivity).

Recommendations

In line with the above comments and suggestions, ASTHO recommend the following:

- S/THA representation in the form of advisory body opportunities—in accordance with the Federal Advisory Committee Act—and/or stronger S/THA stakeholder engagement within working groups and national convenings (e.g., the National Provider Directory Initiative) designed to inform the creation of rules, vet standards, and test implementation.
 - An advisory committee could provide guidance to the RCE specifically regarding public health impacts of contract issues and technical standards. This panel would include representation from public health agencies and organizations at the local, state, and federal level. Input to the board would, ideally, utilize consensus-based processes to ensure that decisions made reflect the interests of the user community at large.
- For ONC to support and promote stronger collaboration among multiple sectors, to include S/THAs, healthcare, and health IT developers and vendors.
- A request for a stronger consensus-based standards process, which includes S/THAs.
- Resources in the form of funding opportunities, federal agency details, or regional coordinating/technical assistance centers that can help S/THAs adopt standards, develop a Health IT infrastructure for safe data exchange and interoperability, and support push and pull data exchange transactions between healthcare, community-based organizations, and public health.
- ONC ISA is lacking public health representation; therefore, we recommend a consensus-based standard process that includes S/THA input.
- Development of a directory of S/THAs that can support or be leveraged for real-world testing and implementation of TEFCA (if those are aligned with S/THA's experiences and population health outcome goals).

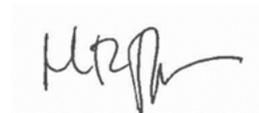
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Thank you for the opportunity to submit comments to ONC's TEFCA Draft 2. ASTHO looks forward to working with the National Coordinator for Health IT, ONC, and the U.S. Department of Health and Human Services to support information exchange and health transformation activities that improve health outcomes in communities. If you have any questions or comments about the above recommendations, or should you provide any additional opportunities to share input—please email Mary Ann Cooney, chief of ASTHO's Center for Population Health Strategies, at mcooney@astho.org.

Sincerely,

A handwritten signature in black ink, appearing to read "M Fraser", is placed above the typed name and title.

Michael Fraser, PhD, MS, CAE, FCPP
Chief Executive Officer, ASTHO

cc: Mylynn Tufte, MBA, MSIM, BSN, North Dakota State Health Officer
Shereef Elnahal, MD, MBA, New Jersey Commissioner of Health
Chesley Richards, MD, MPH, FACP, Deputy Director, Centers for Disease Control and Prevention, Public Health and Surveillance
Jose Montero, MD, MHCDS, Director, Centers for Disease Control and Prevention, Center for State, Tribal, Local, and Territorial Support