June 17, 2019

Don Rucker, M.D.
National Coordinator Office of the National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
330 C Street, SW
Floor 7
Washington, DC 20201


Dear Dr. Rucker:

America’s Health Insurance Plans (AHIP) appreciates the opportunity to provide the Office of the National Coordinator for Health Information Technology (ONC) with comments on Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA). AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

We applaud ONC’s continued efforts to foster trusted exchange of health information through interoperable systems, and we agree more needs to be done to realize this goal. Health insurance providers are committed to finding innovative ways to integrate and exchange data with consumers, doctors, hospitals and other providers. Improving access to meaningful information can help all actors in the health care ecosystem to realize the full benefits of health information technology and data sharing—from improving care coordination to providing access to patient out-of-pocket cost and quality information—resulting in better health outcomes, more affordable care, and higher patient satisfaction.

AHIP supports ONC’s overarching principles for trusted exchange and establishment of a network-of-networks policy framework for trusted exchange of health information. While health insurance providers embrace the movement toward seamless exchange of consumer data, we have significant concerns that the TEFCA’s proposals fails to recognize both the operational complexity associated with building the required technology and the lack of mature standards for the proposed data elements and exchange. We also feel the current
draft of the TEFCA does not adequately articulate the interaction with other federal health information interoperability policies and is not sufficiently fleshed out to effectively execute ONC’s stated goals.

We are concerned that the draft TEFCA would adopt a top-down model that would not take advantage of valuable stakeholder input (via the rulemaking process). We suggest that a better approach is for ONC to build on the strong foundation of the existing Health Information Network (HIN) and Health Information Exchange (HIE) infrastructure and to promote policies that will empower market-driven solutions for health information exchange. We recommend that ONC focus on removing barriers to exchange and providing strong incentives for participation.

AHIP strongly recommends that ONC consider adopting an open, transparent, and participatory governance structure that defines higher-level guardrails, in order for health information networks to operate in a regulatory environment that fosters competition and innovation. To accomplish this, the most effective governance structure would also be flexible and would eliminate or reduce granular, prescriptive, and restrictive components, terms, conditions, and requirements. The burden that granular, prescriptive, and restrictive components, terms, conditions, and requirements create discourages HINs, participants, and participant members to be part of the TEFCA.

Specifically, AHIP and our member health insurance providers have concerns that focus in the following areas:

- Integration of the TEFCA’s principles into the CMS and ONC interoperability proposed rules;
- Incentivizing participation in the TEFCA by defining simplified, general parameters for participation;
- Ensuring the TEFCA does not hinder existing private-sector exchange efforts;
- Aligning the TEFCA’s privacy and security requirements with HIPAA and state privacy and security requirements;
- Development of a privacy and security oversight and enforcement framework for non-HIPAA covered entities participating in the TEFCA; and
- Updating the definitions for Electronic Health Information, Exchange Purposes, and Exchange Modalities to prohibit exchange of competitively sensitive information and focus on use cases where mature content and technical standards for exchange already exist.

Below we provide additional context and recommendations.

Interaction with CMS and ONC Interoperability Rules
Integration with Interoperability Rules

On February 11, 2019, the Centers for Medicare & Medicaid Services (CMS) and ONC issued two proposed rules to support seamless and secure access, exchange, and use of electronic health information. Stakeholders submitted comments only recently—due by June 3, 2019—in response to the proposed rules that significantly overhaul the content, standards, timeframes, and technology for exchange of health information. ONC released Draft 2 of the TEFCA on April 19, 2019, more than two months after the proposed rules. The TEFCA will be integral to the CMS and ONC interoperability final rules, and vice versa, yet it is not clear how the policies are meant to interact.

At this time, it is challenging to provide thorough comments on the TEFCA without a broad-based view of which use cases will flow through which mechanism as well as what will be voluntary and what will be required. For example, ONC proposes a new certification criterion for health IT developers of certified health IT products requiring them to support application programming interface (API)-enabled services on a single patient and multiple patients using the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard. The TEFCA does not specify a standard for sending information from one entity to another. It also does not include population-level data export as one of its required exchange modalities (this was included in Draft 1 but removed in Draft 2). Additionally, the CMS and ONC proposed rules request information on specific patient matching solutions (e.g., algorithms or software) and authority for such requirements. Responses to that Request for Information will impact the technical requirements for patient identity resolution outlined in the Qualified Health Information Network (QHIN) Technical Framework (QTF).

Given the multiple minimum and pending additional required terms and conditions established in TEFCA that would apply to QHINs, Participants and Participant Members, the industry will need to undergo a major effort to update contractual agreements, modify and release Notices of Privacy Practices for consumers, and a host of other activities in order to implement the requirements and expectations across these proposals. We recommend ONC and CMS simplify and integrate the TEFCA and both the ONC and CMS interoperability rules and issue them as a package. Additionally, we request that this package allow for a sufficient timeline for implementation.

Transparency in Development and Updates to the TEFCA

We support the voluntary nature of the TEFCA, but we are concerned that other proposed regulations effectively eliminate that voluntary nature. CMS’s proposed rule would require MA organizations (including MA-PD plans), Medicaid managed care plans, CHIP managed care entities, and QHP issuers in the Federally Facilitated Exchanges (FFEs) to participate in a Trusted Exchange Network (TEN) (84 CFR 7642). While it does not specify the TEN must have
signed on to the TEFCA as a QHIN, Participant, or Participant Member, it is expected the TENs will participate as the TEFCA is key to national interoperability. Otherwise, health insurance providers would be participating in insular TENs that neither connect to a broad array of stakeholders nor meet the underlying need for a single national onramp, and yet meet the CMS requirement to participate in a TEN.

Because ONC presented the TEFCA as a voluntary guidance document, it has not gone through the established rulemaking process. Given the scope of its proposals, the interaction with other proposed rules and the number of healthcare stakeholders it is meant to impact, we believe legitimate concerns exist that the TEFCA drafting process violates the Administrative Procedures Act (APA) (5 USC § 551 et seq.), which requires agencies to publish proposed rulemaking in the Federal Register and provide opportunities for public comment to the federal agency. Furthermore, AHIP and our health insurance provider members are concerned about the process for future updates to the TEFCA as there is similarly no plan for notice of proposed rulemaking after the first version is released. We recognize ONC intends for the RCE to solicit comments, but this process does not provide the same level of public input as is protection included in the APA. We recommend ONC utilize an open, transparent process for updating and revising the TEFCA, leveraging the experience of stakeholders including existing networks and their participants.

Establishing and Open, Participatory, and Transparent Governance of the TEFCA

The TEFCA structure, as proposed, does not have an open, participatory, and transparent governance framework where a representative group of QHINs, Participants, Participant Members and Individual Users are meaningfully engaged in policy, operational and technical decisions that affect them. As proposed, the TEFCA uses a top-down governance, with ONC exerting full control over all policy, operational, and technical decisions affecting the entire US information exchange ecosystem. We strongly recommend that a better approach would be to define an open participatory governance process and structure, including the creation of a TEFCA Oversight Board with balanced representation from all stakeholders, where all required terms and conditions would be subject to public comment and stakeholder engagement through a consistent, open, and transparent participatory governance process.

Encouraging Participation

We believe an incentive-based approach may be more effective than a punitive approach in fostering fulsome participation by a broad array of stakeholders integral to coordinated care, including health insurance providers. Developing the TEFCA to create value to participants will encourage more robust participation and innovation. We are concerned that the overly prescriptive nature of the requirements will discourage, rather than incentivize participation from existing, successful HINs and HIEs and their participants. For example, there is little incentive
or business case for non-HIPAA covered entities, such as third-party application developers, to enter into a QHIN-Participant or Participant Member Agreements. Doing so would subject them to stricter privacy and security standards (for example, the requirements for Permitted and Future Uses of EHI [Sections 2.2.2, 7.2, 8.2]) with little added benefit to them, as there is nothing preventing them from participating in the market outside of the TEFCA’s bounds.

We support the stated voluntary nature of the TEFCA but believe ONC may find it difficult to encourage organizations to sign on to participation as there are no proposed incentives for signing on to the TEFCA. Moreover, creating penalties for non-participation by health insurance providers without comparable requirements on other stakeholders will create an uneven playing field. 

We urge ONC, in collaboration with CMS, to consider simplifying detailed requirements, elevating the conceptual framework of TEFCA to define basic guardrails for participation and information exchange, and establish incentives for participation by a diverse group of stakeholders, including both HIPAA covered entities and organizations not covered by HIPAA. Additionally, we strongly recommend that the TEFCA establish general parameters for participation and information exchange, rather than proposing to rely on detailed, contractual terms that impose multiple conditions and restrictions on information access, use and disclosure.

We further note there are several private sector efforts currently making good progress toward the goal of facilitating trusted exchange of health information between unaffiliated entities, including several existing HINs and HIEs. Many health plans, providers, health IT developers, government agencies, and other stakeholders already participate in one or more of these efforts, which also include common agreements for participation. We are concerned the TEFCA as proposed would significantly disrupt these efforts and the progress they are making toward widespread health information exchange that has been made among existing HINs and HIEs. 

ONC should ensure the TEFCA does not undermine existing private-sector health information exchange efforts and should strive to incorporate existing exchange capabilities, so that private sector innovation can continue unfettered.

Privacy and Security

Alignment with HIPAA and State Requirements

We believe the agreements between existing HIEs, bolstered by the TEFCA, could provide an efficient, effective, and secure route to accomplish CMS and ONC’s interoperability goals while maintaining HIPAA privacy protections for consumers. This can only be achieved if TEFCA is fully aligned with HIPAA requirements. We are concerned that the TEFCA would establish privacy and security requirements under terms and conditions that are above and beyond those defined by HIPAA and other federal and state laws, which would apply to QHINs, Participants and Participant Members, many of which are HIPAA covered entities. We are especially
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concerned that some of these requirements would apply within organizations, going beyond the scope of a trusted exchange framework by impacting internal processes not involved in external information exchange. Evaluating the requirements against those required under HIPAA, incorporating the principles of the TEFCA into the CMS and ONC interoperability rules, and utilizing the rulemaking process for future updates to the TEFCA would contribute to alignment of these privacy and security requirements.

It is difficult to discern where the TEFCA and HIPAA privacy and security rules overlap or differ. For example, additional detail is needed regarding when and how QHINs, Participants and Participant Members should obtain and document patient consent to use and disclose their EHI (as outlined in Sections 7.4 and 8.4) when required by Applicable Law, and how these consent requirements do or do not align with HIPAA. We also note the Exchange Purposes proposed for the TEFCA utilize aspects of the definitions within the Permitted Uses and Disclosures in the HIPAA Privacy rule.

As the Permitted Uses and Disclosures under HIPAA are more comprehensive than the Exchange Purposes in the TEFCA, and there are important differences regarding Treatment, Payment and Health Care Operations (TPO) purposes vs other purposes, we strongly recommend that ONC clarify how it will address exchange of information for purposes outside of the designated Exchange Purposes for both HIPAA and non-HIPAA Covered Entities, and what authorizations may be required for those purposes. Compliance with state requirements is expected to be challenging, particularly as questions are presented about whether state requirements remain intact or would be preempted by a federal, voluntary framework that is not an official regulation. In order to ameliorate these issues, we again recommend that the TEFCA be promulgated as a proposed rule under the APA. Should ONC proceed under the current voluntary structure, we strongly recommend that the TEFCA provide additional detail on how its privacy and security requirements align with HIPAA Privacy and Security rules, as well as state requirements.

Additionally, in absence of preemption, ONC should clarify how the TEFCA’s privacy and security rules are meant to interact with state privacy and security laws. Additional restrictions put on by states are often more stringent than HIPAA, which increases the complexity and timelines for making data available. It is often too difficult for organizations operating across state lines to develop different consent workflows for each state, and the TEFCA will only increase that complexity. Organizations are likely to implement the most stringent state law. We recommend that ONC update the TEFCA to specifically provide guidance on instances where its privacy and security requirements may conflict with state requirements. We recommend ONC clarify, in instances where the laws of the state in which a QHINs, Participant, and Participant Members is located are stricter than the TEFCA’s privacy and security requirements, the QHIN, Participant or Participant member should implement the state
law. QHINs, Participants and Participant Members who operate across multiple states should be able to implement the requirements of state laws.

Oversight and Enforcement

The TEFCA establishes baseline privacy and security requirements that will be shared by all QHINs, Participants, and Participant Members, some (but not all) of whom are considered HIPAA covered entities or business associates. However, we believe there are some gaps to ensuring the privacy and security of exchanged data in the framework given the principles are non-binding and the Common Agreement only permits the removal of an organization from the network. This is particularly true given non-HIPAA covered entities may participate. The process for monitoring compliance with the Common Agreement and adjudicating non-compliance remains uncertain given these documents have yet to be drafted, as they are meant to be published by the Recognized Coordinating Entity (RCE) through the Additional Required Terms and Conditions (ARTCs). Furthermore, enforcement of HIPAA for covered entities as well as an oversight and enforcement mechanism for non-HIPAA covered entities by other federal agencies remains unclear. AHIP urges ONC to work with its fellow federal agencies to clarify how the oversight and enforcement processes will take place among and between federal agencies as well as in tandem with the RCE.

ONC states in the TEFCA Introduction “…the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules.” We support aligning the privacy and security requirements between HIPAA Rules and the TEFCA where possible. We recommend ONC ensure all HIPAA privacy and security requirements are incorporated into the TEFCA requirements and they all apply to both HIPAA and non-HIPAA Covered Entities. While the TEFCA’s provisions may be aligned with HIPAA, they lack the backing of a robust oversight and enforcement mechanism with penalties for violation strong enough to deter bad actors. A non-HIPAA covered entity may agree to the TEFCA’s provisions, but if it violates those provisions, there appear to be no legal or financial consequences for that violation. Requiring data sharing with non-HIPAA covered entities under the TEFCA could put HIPAA covered entities under significant risk. We recommend ONC work with the Federal Trade Commission (FTC) to develop a privacy and security oversight and enforcement framework for non-HIPAA Covered Entities participating in the TEFCA. This framework should build off the HIPAA privacy and security regulations where it can and FTC should seek additional authority where necessary.

Meaningful Choice

ONC requires QHINs, Participants, and Participant Members respect individuals’ exercise of Meaningful Choice by requesting their EHI not be Used or Disclosed unless EHI is required by
Applicable Law to be Used or Disclosed (Sections 2.2.3, 7.3 and 8.3). This “Meaningful Choice” must be communicated to all other QHINs (or, in the case of Participants or Participant Members, to the entity with which they have a signed agreement) within five (5) business days after receipt.

We feel this requirement is excessively burdensome and will, along with other requirements, deter participation in agreements under the TEFCA. This process could disrupt TEFCA participants’ existing consent processes and confuse consumers. There are no established standards for exchanging invocations of meaningful choice, and ONC does not specify how QHIN, Participants and Participant Members are required to document this information. It is also not clear how this provision relates to the consent requirements outlined in the TEFCA (“Other Legal Requirements,” Sections 7.4 and 8.4), implied consent provisions within the HIPAA Privacy Rule, and consent requirements outlined in 42 CFR Part 2.

We recommend ONC narrow meaningful choice to an authorization to disclose information through the QHINs and provide further details on the impact of this requirement on QHINs, Participants and Participant Members, and its relationship to other privacy regulations. We also recommend ONC allow HIPAA covered entities to use their existing consent processes and timeframes to meet this requirement.

Security Breaches

The TEFCA requires that QHINs, Participants, and Participant Members comply with the Breach notification requirements pursuant to the HIPAA Breach Notification Rule at 45 CFR §164.400-414, regardless of whether they are a Covered Entity or Business Associate. We support this proposal. We recommend ONC clarify that legal liability for security breaches that occur as a result of exchange operations under the TEFCA should lie with the QHIN as the primary arbiter of data exchange in this framework.

Comments on Minimum Required Terms and Conditions (MRTCs)

TEFCA Individual and Organizational Definitions

We are concerned the proposed definitions for entities participating in the TEFCA do not sufficiently differentiate between the different kinds of organizations that would be involved in data exchange. Specifically, the distinction between a Participant and a Participant Member is unclear. ONC defines Participants as entities contracting with QHINs, and Participant Members as entities contracting with Participants. However, they suggest in the TEFCA and related materials entities such as health plans, providers, health IT developers and health information exchanges could act as Participants or Participant Members. The MRTCs for Participants and Participant Members are nearly identical, making it difficult to rationalize separating the two
types of participants. **We recommend ONC clarify the difference between a Participant and a Participant Member and provide specific examples of each or consider combining the two concepts.**

We are also concerned with ONC’s proposal to allow Individual Users to have direct relationships with QHINs. It makes sense for Individual Users to have direct relationships with Participants and Participant Members, who are likely to be providers, health plans, and other entities with whom the Individual User has an existing relationship. However, allowing Individual Users to enter into agreements directly with QHINs may result in those individual Users being overshadowed by the other larger and more complex participants in a QHIN. **We recommend the TEFC prohibit Individual Users from having direct relationships with QHINs.**

### Electronic Health Information (EHI) Definition

For the purposes of the TEFCA, ONC proposes to define EHI in the same manner used in the Information Blocking provision of the ONC Interoperability proposed rule. As stated in our comments on the proposed rule, while the Cures Act does not define EHI, “EHI” has long been used by ONC and others as synonymous with electronic protected health information (ePHI).\(^1\) ONC should, whenever possible, leverage the HIPAA definitions and requirements applicable to HIPAA covered entities to help ensure consistency and promote understanding within the healthcare environments. The healthcare industry is familiar with the definition of protected health information (and by extension, ePHI) and has developed policies and procedures around this definition for several years.

Having said this, there are not mature standards across the universe of ePHI, thus it makes sense to start with a subset. The U.S. Core Data for Interoperability (USCDI) is referenced throughout the Minimum Required Terms and Conditions (MRTCs) as the standard for data classes and elements for exchange. However, it does not specify whether all Participants and Participant Members will be required to share all data elements within the standard, or if sharing a limited subset of data elements would be permissible depending on the entity.

We believe Participants or Participant Members should only share the information for which they are the source of truth, and, consistent with HIPAA, disclose only the minimum necessary information (with the defined exceptions). For example, while a health insurance provider may have a lab result it collected from the performing lab or relevant provider as part of a prior

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authorization process, that single lab value out of context may be misleading. Such clinical information should be shared by the relevant lab or provider. Information in paid claims or the administrative decisions related to prior authorization, however, are within the purview of health insurance providers. **ONC should work with health insurance providers to determine an appropriate subset of data elements, to be shared within the context of the Common Agreement.**

Moreover, health insurance providers are not actors under the 21st Century Cures Act and thus should not be held to the same information blocking standard as providers. **We recommend the TEFCA define EHI as a subset of ePHI for which there are defined standards available for actors subject to the information blocking provision.**

We also note that ONC specifically removed payment from the list of Exchange Purposes between Draft 1 and 2 of the TEFCA in response to stakeholder feedback, making inclusion of payment in the definition of EHI irrelevant to the TEFCA’s goals, which focus on exchange of clinical information. To the extent the USCDI includes pricing information in the future, ONC should not add it to TEFCA. In particular, it should not require the exchange of negotiated rates within or across networks. Public disclosure of pricing data could have potentially negative competitive effects that could hinder fair negotiations and drive up prices. Should disclosure of private contract negotiations be included, the cost impacts could be significant, causing serious disruption to our health care system to the detriment of consumers. Moreover, the inclusion of pricing data will deter health insurance providers from participating in the TEFCA. **ONC should not include information relating to negotiated rates in the definition of EHI. In addition we strongly recommend that ONC undergo notice and comment rulemaking for any significant expansion of the definition of EHI for TEFCA purposes.**

**Exchange Purposes Definition**

ONC proposes QHINs, Participants, and Participant Members must be able to request or send EHI for certain Exchange Purposes: Treatment, Utilization Review, Quality Assessment and Improvement, Business Planning and Development, Public Health, Individual Access Services, and Benefits Determination. As ONC notes, Draft 1 of the TEFCA included Payment and Health Care Operations in the list of Exchange Purposes. Based on stakeholder concerns about burden, ONC narrowed the scope of the Exchange Purposes in Draft 2 to only a subset of activities in Payment (Utilization Review) and Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development) as defined in the HIPAA Privacy Rule. While we appreciate ONC’s efforts to streamline the basic requirement and allow innovation beyond that where stakeholders are able, we feel that defining the Exchange Purposes at this level of granularity will create further complexity, increase costs for QHINs, Participants, and Participant Members, and raise additional liability concerns, all of which would discourage participation in the TEFCA.
For example, utilization review should not be defined as a specific Exchange Purpose, as stakeholders, including CMS, are currently working to flesh out content and technical standards to automate prior authorization as a use case within utilization management. ONC should define a broad, high-level set of Exchange Purposes the TEFCA can be used for, leveraging HIPAA Permitted Uses where possible, and not specify the specific elements which are supported by the TEFCA. ONC should allow individual QHINS to determine which of those purposes they will support. We strongly recommend ONC remove the utilization management purpose and consider adding broadly-defined purposes to support improved care coordination between health plans, providers, and patients, including provider directory updates, risk adjustment documentation and quality measure reporting.

Exchange Modalities

ONC proposes to require QHINs to support three types of exchange modalities for exchanging EHI: QHIN Targeted Query, QHIN Broadcast Query, and QHIN Message Delivery. While we support these exchange modalities, we note most HINs and HIEs do not have the functionality for Targeted Query (“pull) or Message Delivery (i.e., “push”). TEFCA should provide for flexibility in exchange modalities, allowing for “push” and “pull” functionality for a single patient or multiple patients as well as message delivery while not mandating their use by QHINs, Participants and Participant Members. We also recommend ONC engage existing HINs on the feasibility of its exchange modalities and update these modalities as needed.

Use or Disclosure of EHI Outside of the United States

The MRTCs Draft 2 currently does not permit QHINs to Use or Disclose EHI outside the United States, except to the extent that an Individual User requests his or her EHI to be Used or Disclosed outside of the United States. We recognize this is meant as a protectionary measure for stakeholders, however we note that many organizations participating in the TEFCA will have business operations outside of the United State. These entities may need to use the TEFCA structure to exchange information internationally in specific circumstances. We recommend ONC provide detailed guidance on circumstances where Use or Disclosure of information outside of the United States would be permitted beyond an Individual User’s request.

Security Labelling

ONC seeks comment on the use of confidentiality codes and security tags and/or reasonable alternatives that would ultimately promote the ability to exchange sensitive data under the TEFCA. We support ONC’s proposal to require security labelling for EHI containing codes for mental health, HIV, or substance use disorder at the highest (document) level as opposed to the individual data element level. ONC should update the TEFCA to provide additional detail on
the security labelling process and mechanisms for safeguarding sensitive information in order to prevent unauthorized data use.

Phased Approach and Pilot Testing

Given the concerns outlined above, we encourage ONC to undertake pilot testing of the TEFCA and consider a phased approach to implementation after testing results have been reviewed. As a best practice in the private sector, pilot testing would provide an opportunity to update the TEFCA based on real-world feedback. It would give healthcare stakeholders confidence the TEFCA is a workable, usable framework for data exchange.

A phased implementation timeline would also allow ONC to incorporate the agreement into existing networks in a controlled way, providing additional opportunities for continuous process improvement. In addition, a phased approach would give ONC time to provide additional detail on the TEFCA’s proposals and update the TEFCA in response to the CMS and ONC Interoperability Proposed Rules. Additionally, it would allow ONC to update the QTF as standards develop and mature. Finally, per our earlier comments on incentives, ONC could work with CMS to permit health insurance providers to count such pilot testing in the quality improvement activities portion of the medical loss ratio. For each of these reasons, we recommend that ONC work with stakeholders and the RCE to develop a timeline for pilot testing and phased implementation of the TEFCA.

Conclusion

AHIP appreciates ONC’s ongoing engagement with stakeholders and the opportunity to provide this feedback on the Draft TEFCA. We look forward to continuing our work with the ONC to achieve the maximum benefit of electronic exchange of health information to improve the safety, quality, efficiency, and affordability of care for those we serve.

Sincerely,

Danielle A. Lloyd, MPH
Senior Vice President, Private Market Innovations and Quality Initiatives