Feb. 20, 2018

Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Draft Trusted Exchange Framework and Common Agreement**

Dear National Coordinator Rucker:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to publication of the draft Trusted Exchange Framework and Common Agreement (TEFCA). MGMA supports the Office of the National Coordinator for Health Information Technology (ONC) efforts to facilitate the deployment and utilization of electronic health information exchange across providers and other stakeholders.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, advocacy and education, MGMA empowers medical group practices to create meaningful change in healthcare. With a membership of more than 40,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

Passage of the bipartisan 21st Century Cures Act creates the opportunity to define and promote the development of a nationwide interoperable health information exchange infrastructure. However, the foundations of interoperability-cooperation, trust, and confidence among all stakeholders who seek to exchange information, must be solidified if the industry is to successfully move forward. With the release of this draft document, ONC has outlined an infrastructure blueprint that we hope will accelerate deployment and adoption of effective and efficient data exchange process.

By proposing a single “on-ramp” for exchange participants, ONC is seeking to leverage the current system of multiple Health Information Networks (HINs) rather than replace them with a single entity. MGMA agrees that moving to a single HIN would significantly disrupt the healthcare system, jeopardize stakeholder infrastructure investments made to date, and require considerable federal dollars to implement. We support the overall approach presented in the TEFCA of establishing a single on-ramp to electronic health information sharing that seeks to facilitate data exchange regardless of the participant’s chosen network. We believe that TEFCA both exploits the considerable progress the industry has made in recent years to electronically exchange patient health information and promotes a set of standards that qualified networks must adhere to. We assert that, once implemented, this framework will create the confidence necessary to significantly expand the exchange of patient data to and from physician practices.

General Comments

As a strong advocate of increased patient safety and improved efficiencies in ambulatory care settings, MGMA has long promoted the adoption of effective, efficient, and affordable health technology. In addition to the clinical benefits associated with health technology, we are hopeful that the availability of low-cost clinical data through an HIN will result in an overall reduction in practice costs. However, significant barriers remain before all group practices and others can begin to reap the benefits of this technology.

As the federal government and the health care industry moves toward adoption of any form of a trusted exchange framework, the following issues should be considered:

- Establish a Quantifiable Return on Investment—For many physician practices, the economics of investing in the technology and workflow modifications necessary to participate with an HIN are unproven. In time when providers are looking at significant cuts to Medicare payments, sharply rising malpractice premiums, and ever-increasing operating expenses, practices continue to be concerned that moving to an HIN information environment may not be financially beneficial to the organization. It is imperative that the HIN business model be established to facilitate physician practice participation.

- Leverage Data Exchange for Additional Purposes—As we move forward to widespread interoperable health information exchange, we anticipate the data will be exchanged for multiple purposes. While data supporting direct patient care remains paramount, clinical data is also needed for a wide array of administrative purposes, including claim submission prior authorization, referrals, care coordination as part of an Accountable Care Organization, Patient Centered Medical Home, or other type of alternative payment model, and data reporting programs (such as the Merit-based Incentive Payment System). Research will also be a recipient of this data. ONC must take into account the multiple uses for clinical data and the potential of an expanded set of roles for HINs within the healthcare environment.

- Identify Appropriate Interoperability Standards—Successful interoperability should include the ability for an electronic clinical system to seamlessly interact with administrative systems. MGMA supports the goal of the ONC to create a secure and interoperable data exchange framework where physician practices and others may depend on the information shared between health information networks. Further, MGMA applauds the concept of creating shared protocols addressing entities not specifically subject to the HIPAA regulations but which will undoubtedly play an important role in trusted exchange including but not limited to, health and fitness device manufacturers, social media, financial and even individual contributors. TEFCA notes that certification using the 2015 Edition Health IT Certification Criteria may be used by Qualified HINs to guide compliance with standards. We concur with utilizing existing standards such as the C-CDA as developed by Health Level 7® International and believe it will be critical to take advantage of existing, proven standards such as those noted as well as avoiding the use of proprietary standards or technology.

- Prioritize Data Flowing to Providers—Practices routinely receive “pushed” data from numerous sources, including HINs, lab facilities, other physician practices, inpatient facilities, and other sources. This can lead to data “overload” and make it extremely time consuming for clinical staff to identify what data needs to be acted on immediately, and what data is merely reference information. For example, a discharge notice from an inpatient facility identifying a diabetic patient who requires immediate follow-up is very different from a routine lab report with no follow-up required. Identification of use cases will be a critical factor in determining prioritized data. Further, it will be imperative to engage both NIN’s and EHR software developers to ensure that solutions leading to data prioritization are explored and implemented.

- Promote the Security of Patient Data—Patients are more concerned than ever about maintaining the security and privacy of their patient's health information. At the same time, providers are embracing the new standards in these areas as mandated by the government. To secure the trust of both patients and providers, HINs must have as one of its core features the maintenance of these well-established HIPAA standards.

- Minimize Exchange Complexity and Cost for Onboarding HINs—While we believe that the TEFCA framework should result in an improved nationwide data exchange process, there is the concern that the HIN participation requirements will prove onerous to potential applicants. HIN participation agreements will change significantly from how they are currently formulated compared to what they will need to be under the new TEFCA infrastructure. TEFCA will require modifications to existing participation agreements and trust frameworks to support provisions such as the additional permitted disclosures of health information by a qualified HINs. There is concern that when qualified HINs have variable permitted purposes in their own participation agreements, exchange between those qualified HINs is limited and may not occur–thus preventing end-users from having a single on-ramp to interoperability. Modifying data sharing agreements most likely will require the HIN to engage legal counsel and/or consulting services to assist them. Applicants could be deterred from joining if there overly complex requirements or if they cannot afford the time and costs necessary to for updating and revising participation agreements.

- Ensure all Provider Specialties and Types have the Ability to Interact with an HIN—Practice partnerships with HINs hold the promise of significant improvements to patient care and substantial efficiencies to providers. As HIN is developed, it is imperative that all providers be encouraged to participate. In particular, safety net providers such as community health centers and rural health clinics as well as smaller physician practices should be targeted by the federal government to receive the assistance necessary to fully take advantage of HIN capabilities. It is critical that these care settings have the ability to participate with the HIN and their patients benefit from the rapid exchange of data. If the participation costs are too high, however, not only will that be a discouragement for these smaller entities to join, but it will also send the wrong message to the provider (and patient) community.

  Suggestions for encouraging small and rural provider participation in HINs include:

  - Low or no cost entry-fee for access to HINs—with all fees waived in cases of safety net and other providers of limited means.

  - Establishment of procedures to certify healthcare software products that they meet certain standards in support of HIN. The current certification process may not be sufficient. An additional process could be developed to permit those vendors seeking to support, for example, small and rural providers, but will not be certifying for Medicaid Meaningful Use of the Quality Payment Program (QPP). This type of certification would provide a higher level of confidence and could be a significant encouragement for these small and rural providers to invest in the software.

  - Federal government incentives to the vendor population to provide low-cost or open source solutions to small and rural providers.

- Align Interoperability with Physician Payment Policies--We strongly support physician payment policies that appropriately compensate those involved in providing patient care across the care delivery continuum. We assert that the appropriate payment policies would be one lever to encourage practices to participate in an HIN and exchange their patient information with other care settings.

Innovative payments models for physicians, whether it be an ACO, Patient-Centered Medical Home (PCMH), or other appropriate value-based care model, have the capability of expanding practice participation with HINs. However, successful participation in these payment models should not be contingent on HIN participation. HIN interaction should be an optional component of any payment or incentive program, as not all providers may have access to a qualifying HIN.

- HIN Financial Sustainability--All stakeholders have a role to play in sharing the costs of building and supporting HINs as everyone will ultimately derive benefits. Initially, the federal government should take a leading role in providing grants to local/regional consortia to pilot-test this local HIN capabilities. The federal government should also ensure that all federal health care programs work with HINs. While start-up funding provided by the federal government would be extremely helpful to local HIN groups, unless this federal funding is guaranteed for a long period of time, it would not be the optimum financial model. Clearly what is needed is a business model that sustains an HIN for the long term. This business model might include federal dollars, but this should typically not be its sole source of financing.

  Another challenge is that the business sustainability of HINs has not been clearly established through any of the various funding approaches implemented to date. Recognizing that there is a distinct role to play for government in the development and deployment of HINs, the HIN environment should not be funded solely by creating short-term incentives for its use. If it is financed without corresponding changes that re-align clinical incentives for its use, providers will remain unlikely to utilize the network to support patient care, thus crippling opportunities for wide adoption. The same is true for the software applications that connect to the HIN environment—free or low-cost applications alone will not result in rapid and widespread adoption as long as the financial incentives for users are disproportionate to their immediate benefit.

  The long-term financial sustainability of HINs will also depend on addressing data ownership issues. Theoretically, the value of the data flowing through the network could be tapped as a source of funding (for example, market researchers might be interested in obtaining data to analyze business prospects for different products in different areas). However, who owns which data to sell at what price? The issue is complex because various stakeholders will wish to protect their proprietary interests in their data.

  We encourage ONC to consider a number of financing options for the development of HINs as well as their ongoing maintenance and support. For example, the cost-sharing model could be modeled after the national highway system, a model that includes a combination of federal and state support, tolls, car and gasoline taxes, etc. Relying too heavily on a single source of financial support could leave an HIN vulnerable to a changing political or economic environment. It is critical, however, that whatever approach is adopted to ensure the long-term financial viability of the HIN not add any net cost to healthcare.

  It would, however, be unfair to expect providers to pay the majority of the costs associated with HIN participation. Whether it be a per-record toll-like fee for accessing the data, HIN access fees, fees for the purchase of third-party interface software, or the expense associated with purchase and upgrade fees for EHR software, providers are currently shouldering the majority of interoperability costs. While these expenses may not serve as an impediment for larger organizations, they can be a significant barrier to participation for smaller physician practices. Any assistance from a policy standpoint to mitigate costs of participation and certification requirements from vendors could expand the field for active data exchange participation.

While providers benefit from having faster access to better data, others in the healthcare ecosystem also benefit from effective interoperability. Health plans can save money as interoperable systems produce improved care coordination, fewer duplicative tests, and fewer hospitalizations and re-hospitalizations. Of course, patients themselves can benefit tremendously by having the care delivery system be more effective and more efficient. Ultimately, an interoperable healthcare system must be treated as a public utility-one where everyone benefits, and therefore everyone should share in the cost of construction and maintenance.

- Incentivizing Exchange Participation--There are a number of ways to encourage providers and vendors to participate in the exchange of data. These include:

  - Creating appropriate financial incentives to reflect the reality of this new HIT and data interchange environment where providers now work. Financial remuneration for this work, payment incentives and payment for e-consultation or incentives for use of HIN-related services should all be explored as potential levers to increase provider participation with HINs. Activities such as these could be encouraged through incentives and reimbursement while also addressing cost reduction through focus on more cost-effective activities. At the same time, we oppose punitive measures such as payment adjustments for those providers unable to engage in these activities.

  - Addressing continuing liability concerns, as these are clearly a barrier for increased provider participation with HINs. Liability issues include interstate data sharing, veracity of the data relied upon for clinical decision-making, completeness of data, and integration of patient-supplied information into the data stream.

  - Prohibiting provider coercion from third parties to either participate with an HIN or to purchase specific software. We have heard some disquieting reports from members who have been aggressively approached by their local HIN—linking participation with issues such as patient referrals, lab tests and access to inpatient facilities. Other members report the HIN requiring the purchase of a specific vendor's EHR product prior to being permitted to participate with the HIN.

  - Encouraging provider participation by incentivizing the sharing of data through an HIN. Although CMS has encouraged market competition through their Medicare programs (for patients), it is challenging to convince market competitors to willfully share their patient's data with a real or potential competitor. In today's market environment, providers must have a compelling reason to exchange data with their competitors.

    Factors that could impact this competitive environment would be (a) that every competitor will be given the same access to the same data, (b) that strict protocols be in place prohibiting the use of HIN data for marketing purposes; and (c) that both the sender and receiver of the data are financially rewarded. In addition, developing a provider-focused ROI case that includes who is involved, what data is exchanged and the business rationale may assist in breaking down market competitor barriers.

- Provider Directories--Should the government move forward with any form of provider directory for the purpose of HIN participation, there are a number of considerations that should be taken into account:

- Requiring that the process incorporate an "opt-in" provision for providers instead of an automatic participation through the Medicaid Meaningful Use or QPP attestation process. Those providers not participating in these programs could be solicited for their willingness to be included in the HIN directory through Medicare contractors (Medicare enrollment and reenrollment), medical specialty registries, and potentially other communications.

- Expanding the current National Plan and Provider Enumeration System (NPPES), if the goal is to create a single national provider directory for HIN use. We encourage the NPPES is well known by the provider community and could be expanded to include HIN functionalities. Whatever the directory selected, we strongly encourage the government to require only a minimum number of data elements and ensure that the security of the information is maintained, with unauthorized individuals not having access to this information.

- Leveraging existing private sector directories. For example, the Council for Affordable Quality Healthcare (CAQH) ProView credentialing database currently includes more than 1.4 million providers. Although Medicare continues to refuse to participate in this collaborative effort, virtually all of the commercial plans derive their credentialing data from ProView.

- Discouraging the development of any form of proprietary (state-based or regional) HIN directories as the goal should be the ability to move patient data to where it is needed, regardless of the location of the data or the recipient provider.

- Providing education and guidance to providers on the HIN directory, with a focus on the value to patient care and practice efficiency of achieving interoperability.

- Consultation with the Physician Practice Community—It is critical that physician practices play an integral role the development and deployment of the national HIN development and deployment strategy. With the vast majority of all health care being delivered in medical practices, the success or failure of these initiatives will depend heavily upon their ability to transmit high quality data to these physicians in a timely and secure manner. MGMA encourages the agencies to continue its very positive outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Patient and Provider Outreach—The success or failure of HINs will depend, in part, to the ability of the federal government and the HINs themselves to get both patients and providers to understand and support the system. It is imperative that these two critical stakeholders are well educated as to the capabilities and the privacy components of the exchange. MGMA recommends CMS and ONC work with the appropriate consumer and provider associations as well as the popular media to put forth a consistent message on this important change in the health care system.

Comments on the Specific Questions Included in the Draft Framework

ONC question:

We recognize that important health data, such as that included in state Prescription Drug Monitoring Program (PDMPs), may reside outside of EHR/pharmacy systems. In such cases, standards-enabled integration between these systems may be necessary to advance, for example, interstate exchange and data completeness. As such, we invite comment on the following questions: How could a single "on ramp" to data that works regardless of a chosen HIN support broader uses for access and exchange of prescriptions for controlled substances contained in PDMPs? Given the variation of state laws governing PDMP use and data, should interstate connectivity for PDMP data be enabled via a TEFCA use case to address the national opioid epidemic?

MGMA response

In terms of an important use case for data exchange, few rival the challenge associated with the opioid epidemic facing this nation. State PDPMs are an important tool for combating this epidemic, yet clearly more can be done by using fully interoperable solutions. While there does exist some coordination between state PDMPs, there is no doubt that TEFCA presents a unique opportunity to leverage a single on-ramp for providers to participate in nationwide controlled substance monitoring. Due to the fact that there is wide variation of state laws governing PDMP use and data, either a single approach would have to be agreed to voluntarily by the states, or the federal government would be forced to require the states to participate in this type of national approach. As the opioid epidemic impacts all states and all state budgets, there could be considerable interest in a national solution that improves controlled substance monitoring.

Further, not only should there be a PDMP process that is comprehensive and span all states and territories, but the provider interface must be seamless and user-friendly if the monitoring process is to be effective. We urge ONC and all other government agencies with PMDP jurisdiction to solicit feedback from the provider community regarding web interfaces and the end user experience.

ONC question:

Are there particular eligibility requirements for the Recognized Coordinating Entity (RCE) that ONC should consider when developing the Cooperative Agreement?

MGMA comment:

TEFCA includes a draft description of the Recognized Coordinating Entity (RCE) that would operationalize TEFCA and create a single Common Agreement. ONC is proposing that qualified HINs would voluntarily agree to abide by the single Common Agreement in order to participate in the information sharing among the networks. As laid out, the RCE will have significant oversight, enforcement and governance responsibilities for each of the qualified HINs who voluntarily adopt the final version of the TEFCA. While it is likely that competition and other market drivers will strongly encourage individuals HINs to decide to become a qualified HIN and conform to the principles and procedures outlined in TEFCA, it is unclear in the document what enforcement mechanisms ONC can deploy to keep HINs aligned with the TEFCA requirements.

In terms of the identified RCE, it will be critical for this entity to have a number of characteristics if it is to successfully administer the trusted exchange framework. The named RCE must have:

- **Financial sustainability for the next several years**. ONC must accurately assess RCE costs and provide the resources necessary to ensure success of the program;

- **Diversity**. There may not currently exist any entity that has the requisite diversity to meet all of the requirements laid out in the TEFCA. As a result, we urge ONC to consider a consortium of organizations that could work together to meet the varied needs of the RCE;

- **Transparency**. All RCE actions and decisions should be transparent and these decisions and actions should accessible to the public;

- **Support from key stakeholder groups**. These include the HINs themselves but also patient groups, vendors, physician practices, and other providers. If there is a lack of trust from any one of these groups, the legitimacy of the RCE could be called into question; and

- **Accountability**. As the RCE will provide oversight of the HIN community, there must also be oversight of the RCE itself. We urge ONC to implement a process of RCE assessment and permit the public to review and provide input on RCE actions.

In addition, ONC states in the TEFCA, "Certification enables End Users to have confidence that their health IT will support interoperability for the appropriate use cases and helps enable the exchange of Electronic Health Information in a structured way." We fully support this concept and agree that certification of HIN's will be a critical component of an effective and secure exchange network. In particular, there must established a comprehensive third-party review of HIN security policies and procedures. Without that level of verification, the network runs a higher risk of unauthorized disclosure of patient information with the result decrease in patient and provider trust.

MGMA recommends that the ONC and the RCE utilize the Electronic Healthcare Network Accreditation Commission (EHNAC) to be the authority to administer an HIN-specific accreditation program. EHNAC's proven track record of developing and administering accreditation programs for HINs and many other healthcare exchange entities position them to assist the RCE in accrediting and monitoring compliance.

EHNAC has specific and unique competency in the accreditation environment as evidenced by their current programs for Health Information Exchanges (HINs), Health Information Service Providers (HISPs), Electronic Prescription of Controlled Substances (EPCS), and Electronic Healthcare Networks (EHNs). Currently, the organization offers 18 specific accreditation programs to a wide variety of industry stakeholders. Given the role of an accrediting body under TEFCA, EHNAC would ensure that HINs would be tested for their adherence to the six principles outlined in Part B of the draft framework: 1) Standardization; 2) Transparency; 3) Cooperation and Non-Discrimination; 4) Privacy, Security, and Safety; 5) Access; and 6) Data-driven Accountability.

RCEs and HIPAA

In the draft TEFCA, ONC outlines that while qualified HINs may operate as a Business Associate to its exchange participants, a qualified HIN could also have exchange participants who are not themselves Covered Entities or Business Associates. As drafted, TEFCA appears to be comprehensive enough that under both scenarios, Covered and Non-Covered Entities are enabled to appropriately and securely access health information, as the terms and conditions to enable this broader exchange are specified. ONC concedes, and we concur, that this is not a new situation for most HINs, as most have participation agreements that utilize broader terms to enable both Covered and Non-Covered Entities to utilize their networks.

ONC question:
Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?

MGMA comment:

A successfully interoperable health system must have, as one of its foundations, the accurate identification of patients. One of the most critical challenges for the healthcare industry is accurately identifying the patient and tying that identification to the right designated record set held by a healthcare provider. Even though HIPAA required the Secretary to establish a National Patient Identifier in 1996, the industry still does not have a standardized, unique patient identifier. Interoperability – electronic healthcare information exchange – is difficult to achieved across healthcare providers for a patient's comprehensive medical record in the absence of standardization of patient identification or other widely accepted processes used to achieved proper matching. This is an acute problem as the nation continues to invest in EHR technology when the patient's electronic "address" differs across EHR systems. While numerous patient-matching and identity management initiatives exist (e.g., ONC, NIST, etc.), there is no common strategy that has been adopted by the healthcare industry.

We urge ONC to convene industry stakeholders to:

- Identify best practices related to patient matching by reviewing current approaches to patient matching and identity authentication;
- Initiate patient matching pilots to identify one or more patient matching strategies (i.e., algorithms) that best meets the needs of the industry;
- Explore the potential of making one or more of these strategies freely available to the public. Competition between vendors in the HIN space should not be based on what patient matching strategy they deploy; and
- Launch a consumer awareness and education campaign regarding these strategies.

Conclusion

In conclusion, this is a historic opportunity to reform and revitalize the nation's healthcare system and MGMA supports the overall objective of deploying HIT in physician practices and expanding opportunities to share clinical data between physician practices and other care settings. Considerable work must be accomplished in order to make effective HIT widely available as there are numerous technical, legal, and logistical barriers to the establishment of a national trust exchange framework. Should the requirements for participation in HIN be overly stringent or the process too onerous, the government runs the risk of excluding a significant percentage of physician practices and HINs from participation. Through implementation of appropriate policies, processes, and incentives, as well as outreach to physician practices and other key stakeholders, we believe that the nation's health information exchange infrastructure can achieve the goals and vision laid out in this document.

We thank you for taking on the formidable task of reshaping public policy to create a healthcare infrastructure that will lead to improved patient care and more efficient delivery of that care. We

look forward to continuing work with ONC and other federal agencies to facilitate physician practice transition to EHRs and HINs, and ensure that the promise of improving the nation's healthcare system through technology becomes a reality. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs