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June 17, 2019

Alex M. Azar II
Secretary, Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Secretary Azar:

Thank you for the opportunity to respond to the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2* and the coinciding policy and technical approaches being taken by Office of the National Coordinator (ONC) in an effort to enable the nationwide exchange of electronic health information (EHI), as mandated by the *21st Century Cures Act*.

CoverMyMeds, part of McKesson Prescription Technology Solutions, is the leading medication access company, helping patients get the medications they need to live healthy lives. We help patients navigate medication access throughout their wellness journey through comprehensive HIT solutions such as electronic prior authorization and real-time benefit check. CoverMyMeds seamlessly connects the health care network to help reduce prescription abandonment and increase speed to therapy. CoverMyMeds' network includes more than 500 electronic health record systems (EHRs), 96% of pharmacies, 700,000 providers and most health plans and PBMs. By facilitating appropriate access to medications, we help customers avoid billions of dollars each year in administrative waste and avoidable medical spending caused by prescription abandonment.

General Comments:

CoverMyMeds is pleased that the ONC has released *The Trusted Exchange Framework and Common Agreement Draft 2;* the *Minimum Required Terms and Conditions (MRTCs) Draft 2*; the *QHIN Technical Framework Draft 1* and applaud the ONC for their efforts to provide a single "on-ramp" to nationwide connectivity. However, we are not confident that these efforts will result in the intended outcome of fluid interoperability between patients, providers, payers, developers and other stakeholders.

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Specifically, there are still too many variables related to each proposed QHIN and what seems to be their ability to create specifics within the Common Agreement (CA) that correlate to their network and the data that stakeholders would have access to within their network. This type of variability is what is present in the industry today and a reason for the lack of interoperability and data blocking.

CoverMyMeds supports consumers rights to their healthcare and the ability to directionally share their information as they deem appropriate. Although not the biggest barrier to interoperability, the lack of standard, consistent requirements for patient's or their agents to request and receive the patient's record does create barriers. Organizations are using privacy and security as a means to engage in anti-competitive practices by applying unique requirements to access patient information, even with patient consent. A standard, created through HHS/ONC rulemaking, and required to be utilized by all would help in the removal of this barrier.

Specific Comments to the Six Principles within TEFCA Draft 2

Standardization

CoverMyMeds concurs with ONC on the use of adopted standards and best practices as established by standards development organizations (SDOs) to exchange EHI. When no standard is available to do so, information exchange, in or outside of a HIN should occur using voluntary consensus or industry standards that are readily available to the stakeholders who are exchanging said information.

Transparency

CoverMyMeds is concerned that we are not stepping forward but will remain status quo with this ONC statement, *"All parties desiring to exchange EHI through a HIN should know, prior to engaging with a HIN, the responsibilities of being a participant in a HIN and the protections that have been put in place to ensure that privacy and security requirements are followed. HINs should make these and other terms and conditions for participating in their network easily and publicly available via their website; meaning they are accessible to the general public."*

All networks should work commonly to allow for and to exchange EHI. With this concept, we concur; however, it seems that within this rulemaking a common agreement amongst stakeholders to exchange with each HIN is really not where we are at in this rulemaking. This rulemaking is still permitting one-offs agreements of exchange between the QHIN and those that wish to obtain and or exchange information.

To ensure effective request, response and exchange of information amongst all stakeholders, if a patient or the patient's agent has given consent for said exchange or release of the patient's information, then the information should be exchanged in the same manner from one HIN to the next. The same privacy and security protocols should be present from one HIN to the other, one stakeholder to the other. HINs

and other stakeholders should not impede the ability of individuals to access and direct their EHI. This creates true transparency.

Cooperation and Non-Discrimination

We concur with ONC that HINs should not treat individuals' EHI as an asset that can be restricted in order to obtain or maintain a competitive advantage. HINs and other holders of patient information should not withhold health information requested for treatment, payment, and health care operations purposes from health care providers or health plans that are outside of their preferred referral networks or outside of a value-based payment arrangement. Additionally, technology should be implemented to create data reciprocity.

To our point made above related to transparency, while HINs must comply with applicable laws (including the applicable HIPAA Rules), they should not use contract provisions or common agreements or proprietary technology implementations to unduly limit connectivity with others, including the patient or the patient's agent, including third party applications.

As reported in ONC's Data Brief No. 47, more and more patients are being offered access to their medical record. With the advances in technology that enable the patient and their provider to make informed decisions about their health care, it is vitally important that those stakeholders who hold information beneficial to the patient's journey, open up that data to be surfaced by such technology. For example, real-time benefit check, at the point of prescribing is a reality today in the marketplace. This technology is a catalyst to provide the patient and/or their provider information they need to make informed choices about obtaining their needed medications, at a price point the patient can afford.

Privacy, Security, and Patient Safety

At the center of the exchange of health information should be the patient or their agent. If a patient, gives consent for the release and exchange of their specific EHI, the exchange should take place in a timely manner. Section 2.2.3 of draft 2 references five (5) days as the timeframe in which to share EHI based on receipt of a patient's request, i.e. Meaningful Choice. Waiting for five (5) days to have information shared with a physician or directly to the patient or their agent, is too long. Many times, patients and their physicians need the requested information to take action on the next step in their healthcare journey. With the advancements in technology and use of standards, the request and receipt of EHI can happen in real-time. We encourage ONC to shorten the timeframe in section 2.2.3 taking into the consideration the availability of standards and best practices, like APIs, that make this kind of information accessible. We also recommend that ONC clarify that meaningful choice is not inclusive of treatment, payment and healthcare operations as this is already covered under HIPAA law.

In previous comments to ONC, we have communicated that the lack of data transference is not due to the lack of technology and standards in which to do so. In our experience, it is predominantly the lack of willing trading partners.

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As noted in this draft, "the Cures Act emphasizes the need to improve patients' access to their EHI. Many non-HIPAA entities, such as developers of smartphone apps, offer useful and efficient services to individuals who elect to use them as a means to access their EHI. These services allow individuals to play a greater role in managing their own health and shopping for coverage or care. It is essential that individuals have trust in these organizations and the use of these technologies that can ultimately enhance the quality of their care." As also detailed in this draft, the Common Agreement that would have to be agreed to by the app developer, will provide a sense of trust but again, if there are variables to the common agreement between the multitude of anticipated HINs, then we do not have a common agreement and fluid exchange of information. We have one-off agreements which is what is present in the industry today.

Access
CoverMyMeds concurs that third-party applications should not be limited from accessing individuals' EHI via an API when the application complies with the applicable data sharing agreement requirements and the individual has directed the entity to disclose a copy of ePHI to the application. We also concur that it is important for patients to be able to obtain information about how their EHI has been used and disclosed. We further advise the ONC that this request and response process should happen in real-time and five (5) days as referenced in this draft is not a real-time exchange.

Patient Identity Resolution
While CoverMyMeds does not think patient-matching is the most significant barrier to interoperability, we do support efforts to identifying scalable patient matching options. We encourage ONC to explore implementation of a patient matching solution that allows disparate healthcare organizations to exchange patient information across enterprise boundaries. CoverMyMeds recommends ONC support industry-led efforts to have reliable identity matching.

Conclusion

We are appreciative of the opportunity to provide comments to this proposed draft. Given the variables still present related to the operational issues to implement TEFCA, we believe this it is premature to mandate the use of TEFCA and recommend ONC keep TEFCA voluntary.

As an innovator in the healthcare technology and information sharing space, we are happy to serve as a resource to the ONC as we continue the process to address the important issues outlined in the TEFCA draft 2.

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If you have questions, please contact Kim Diehl-Boyd, Senior Director, Industry Relations and Government Affairs, at kdiehlboyd@covermymeds.com or 615-663-5579.

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