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Don Rucker, M.D. National Coordinator for Health Information Technology Office of the National Coordinator U.S. Department of Health and Human Services 330 C ST SW Mary Switzer Building; Mail Stop 7033A Washington, D.C. 20201

June 17, 2019

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

Dear Dr. Rucker:

Thank you for the opportunity to submit the following comments in response to the ONC *Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA)*. Drummond is a respected test lab and certification body, fully authorized for testing and certification of Health IT by the Office of the National Coordinator under their Health IT Certification Program. As a recognized industry leader and ONC-ACB, we have unique insight into the ONC certification program, the state of interoperability, and common end user challenges.

Our details comments are attached and address the following: The Common Agreement's Relationship to HIPAA TEF Draft 2 Minimum Required Terms & Conditions (MRTCs)

We appreciate your consideration of our comments and look forward to our continued work with the ONC, health IT Developers and the provider community to advance interoperability throughout our nation's healthcare system.

Sincerely,

John Valutkevich Interoperability Program Director Drummond

The Common Agreement's Relationship to HIPAA

The Drummond Group commends ONC on its inclusion of language and reference to the credentialing of 3rd party applications (apps) such as those provided by developers of smartphone apps. We acknowledge that the proliferation of these apps has been voluminous and in some cases with nefarious intentions. An end user should be able to trust the app and its intent when utilized for health information exchange. However, it is not always apparent when viewing the app in a "store", nor can all reviews be trusted.

By designating these apps as either Participant or Participant Members of a QUIN, it provides assurances that a QUIN will credential the app to IAL2. This designation safeguards not only the end user, but also the QUIN itself, from becoming a target of identity theft or fraud. Further, it allows QUINs to offer a credentialing program that could create a publicly available "preferred app" listing for participants and individual users, thereby removing some of the uncertainties about which apps are approved for use in exchanging with the QUIN.

TEF Draft 2

The Drummond Group agrees with the principle that *Health systems and providers may want to use HINs to decrease the number of discreet interfaces they have to build to exchange EHI*. Yet we feel a comment is warranted to address the supporting statement that *HINs should provide the ability for their participants to both pull and push population level records*. A one-size fits all requirement is being applied, which is not consistent with the way all HINs are chartered. For example, CommonWell and Carequality are nationwide query-based health information exchanges with the ability to query for a record(s) and pull forward to an EHR. These frameworks do "push" a query, but "pull" records. Conversely, a state HIN such as in Massachusetts (Mass HIway) offers "push" technology through Direct Messaging to allow providers to push immunization information from the EHR to the state repository that seves as a qualified clinical data repository (QCDR).

National HINs and statewide HINs represent two distinct use cases for exchange and should not be subject to the same requirements for pull and push. When addressing other exchange use cases in the TEF such as providing quality measurement services and payer systems and group health plan access, the pull and push transactions may vary. In many of these push instances, a repository exists and is maintained by the HIN or the participant; however, this is not always the case. The TEF aptly recommends the use of APIs to accomplish these larger population level records over time, which in some cases HINs can and do support. Yet again, the use case is too specific. We therefore recommend additional language around the definition of a push transaction as provided by a HIN. Specifically, a HIN may meet the definition of a push transaction by offering a service that is a query and/or delivery of a record. Accordingly, the push query may be IHE, Direct or HL7 API based.

Further, the statement that a HIN's ability to support both push and pull population level records is matched with the concept that *this decreases the amount of time a clinician's resources are devoted to such activity and makes more time available for providing efficient and effective care*. In principle this is true, but we believe the ownness should be on the configuration at the EHR level and not on a HIN to be all encompassing. Many EHRs today offer embedded workflows to pull at registration and push upon discharge, requiring little to no clinician intervention, reconciliation of data notwithstanding. These EHRs can be configured to connect to one or more HINs or repositories which are traditionally not one and the same and accordingly require different pull or push technology. Reduction in the amount of connections is already occurring with the rise of more sophisticated HINs such as Mass HIway, Carequality and CommonWell, to name a few. Yet, as described above, their use cases are different and subsequently require the EHR to

connect differently.

Minimum Required Terms & Conditions (MRTCs)

The Drummond Group recommends additional language under Section 6.2.4 Identity Proofing (ii) Participants/Participant Members, that ties back to the intent within The Common Agreement's Relationship to HIPAA section. Specifically, we request the creation of an example statement under the section similar to "For example, IAL2 identify proofing is required for a 3rd party app requesting access to a QUIN."