

June 17, 2019

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

**RE: *Collective Medical comments on Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFv2)***

Dear Dr. Rucker:

On behalf of Collective Medical (Collective) we appreciate the opportunity to respond with comments to Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFv2). We are grateful for ONC's leadership in challenging areas, diligence in covering a wide range of important topics, and openness to seek and respond to industry perspectives through this process.

As an initial comment, we express strong support for the policy objectives and the general approach ONC is taking with the Trusted Exchange Framework, Common Agreement, and related content in the TEFv2 draft. In our view, TEFv2 improves upon and advances the proposals included in Draft 1 of the Trusted Exchange Framework and Common Agreement (TEFv1). We believe having a common set of legal terms and conditions and technical standards for basic connectivity will provide a substantial benefit across the health care ecosystem.

#### **BACKGROUND ON COLLECTIVE MEDICAL**

Collective has developed the nation's most effective network for real-time care collaboration between covered entities. Collective provides real-time, risk-adjusted event notification and care collaboration tools that covered entities across 31 states use to engage in care coordination, case management, and other treatment, payment, and health care operations activities.

The Collective Network now includes thousands of covered entities across all points of care, supporting care teams across hospital emergency departments, inpatient acute care settings, post-acute settings, primary care and FQHCs, behavioral health providers, ACOs, Medicaid managed care organizations, and health plans. In addition, Collective has also entered into collaborations with dozens of statewide, regional, and health system health information organizations that operate public or private health information exchange networks (HIOs) and electronic medical record or other health information technology vendors (HIT vendors), which include a variety of data sharing and other collaborative activities.

Collective also works closely with state hospital associations, the national association and state chapters of the American College of Emergency Physicians, state Medicaid agencies, and other public stakeholders (e.g., state primary care associations, state-based associations of behavioral health

providers, etc.) as partners or collaborators as we expand the Collective Network into their geographies and with their members or constituents, with a goal of connecting them and enabling them to engage in expanded care coordination activities. With acute pressure from the opioid epidemic in many of our geographies, we have worked with our covered entity customers and public stakeholder partners to connect the Collective Platform with state prescription drug monitoring program (PDMP) databases. We currently query various state PDMP databases for approaching 1,000,000 patients per month and are increasing rapidly.

Because we serve covered entities, public stakeholders, HIOs and HIT vendors across the continuum of care and in geographies across the nation, we understand first-hand the challenges that result from information blocking practices and the detriments that such activities create for healthcare providers and patients. Moreover, we have seen many wonderful advancements in interoperability and sharing of PHI across the nation and we believe strongly that advancement of Open APIs as required by the Proposed Rule will significantly accelerate the ability of health plans, providers, and patients to work together to improve our health care system.

### SUMMARY OF COMMENT TOPICS

Our comments address the following topics: (1) Exchange Purposes, and (2) Minimum Necessary Requirements.

### COMMENTS

#### (1) Exchange Purposes.

In TEFCA Draft 1 (TEFCAv1), ONC initial proposed the scope of Exchange Purposes to include “treatment, payment, and health care operations” as defined under HIPAA. We believe ONC’s proposed change to limit the scope of the term Exchange Purpose to include a subset of “payment” and “health care operations” activities is a significant mistake, and urge ONC to return the definition to full include full Treatment, Payment, and Health Care Operations (full TPO) purposes.

ONC indicated that many commenters to TEFv1 “felt that requiring full Payment and Health Care Operations Exchange Purposes were too burdensome to implement immediately.” (TEFv2 at p. 15). While we have not had opportunity to review the comments ONC received to TEFv1, we find it difficult to believe that, with regard to electronic health information (EHI) which is currently available through existing data integrations, ***the scope of how EHI can be used*** places any kind of legal, technical, operational, or legal burden on any stakeholders across the country. In our view, where EHI is available through an existing data integration, there is very little (if any) additional effort needed by a disclosing entity whether the Exchange Purpose is “full TPO” as proposed in TEFv1 or “limited P+O” as proposed in TEFv2.

We are aware of many stakeholders across the country who have various degrees of discomfort with sharing information for “full TPO” purposes, but in our experience this discomfort stems from reasons much more related to anti-competitive or counter-party economic negotiations—i.e., some of the main drivers of prototypical information blocking

practices---than because of technical, operational, or other burdens. Where ONC's decision to include limited P+O definitions in TEFv2 is driven by this concept of burdens on disclosing entities, we believe it is based on a mistaken assumption.

In fact, we believe that the limited P+O scope of Exchange Purposes likely places more burden on stakeholders generally, because an entity receiving EHI will need to implement controls or processes to ensure that the EHI it receives from a QHIN is not used for a purpose which is excluded from an Exchange Purpose, but which is permissible for the entity under the HIPAA Privacy Rule. In addition, even with ONC's expression of intent to expand the definition of Exchange Purposes to full TPO in the future, in the meantime it will create more burden from a contract drafting, negotiation and interpretation standpoint because many stakeholders across the country have based their "permitted purpose" for exchange of EHI on the full TPO standard.

While ONC has been clear that parties may authorize a broader set of purposes than the Exchange Purposes specified in TEFv2, this will nonetheless still very likely create confusion and disagreement about how EHI may be used where parties have permitted purposes which are broader than full TPO.

In particular, we believe the following exclusions from TEFv2 definition of Exchange Purposes are problematic:

- "reviewing the competence or qualifications of health care professionals, evaluating practitioner or provider performance, health plan performance, etc."
- "business management and general administrative activities" (e.g., customer service, resolution of internal grievances, compliance activities)
- "conducting or arranging for medical review, legal services and auditing functions (e.g., fraud and abuse detection")

Each of these purposes represent uses of EHI which are legitimate and widespread activities, and which do not create any additional burden on disclosing entities. At a minimum, we recommend that ONC add these purposes to the definition of Exchange Purposes in TEF.

## **(2) Minimum Necessary Requirements.**

We support including of requirements for QHINs, their Participants, and downstream entities and users to comply with the minimum necessary standard in the HIPAA Privacy Rule (Minimum Necessary Requirements). However, we recommend that ONC clarify that while a QHIN or one of its Participants must comply with the Minimum Necessary Requirements when disclosing EHI, this requirement is satisfied by its reasonable reliance on the representations of a requesting entity that the scope of its request for EHI is consistent with the Minimum Necessary Requirement. We believe there is some risk that a QHIN or Participant may interpret this responsibility as a greater burden than they already have under the HIPAA Privacy Rule to exercise heightened scrutiny with regard to the scope of a request for EHI. This could both be administratively burdensome, create risk of good faith disagreements between a requesting and disclosing QHIN or Participant with regard to appropriate scope of disclosure, and create an opportunity for a QHIN or Participant to use Minimum Necessary

Requirements as pretext for declining to share EHI, when in reality the intent is to engage in information blocking for anti-competitive, economic, or other invalid purposes.


We believe that ONC can largely eliminate these risks by clarifying that the primary burden for complying with the Minimum Necessary Requirements lays on the QHIN, Participant, or downstream entity which is requesting or using EHI. Certainly in the case of entities which are Business Associates or Covered Entities under the HIPAA Privacy Rule (the vast majority of entities to which these provisions will apply), there is low risk that they will request or use EHI in a manner inconsistent with the Minimum Necessary Requirements since there are stiff regulatory penalties associated with such conduct.

We recommend that, at a minimum, ONC provide commentary (1) making clear that a disclosing entities' responsibility under the Minimum Necessary Requirements to review of a request for disclosure of EHI is no greater under TEFv2 than already exists for a Covered Entity or Business Associate under the HIPAA Privacy Rule, (2) cautioning stakeholders from exercising unreasonable scrutiny or refusing to rely on the reasonable, good faith representations of an entity requesting EHI (absent some good cause to do so), and (3) explaining that efforts to use the Minimum Necessary Requirements as a pretext to avoid disclosure of EHI could constitute information blocking.

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Collective respectfully submits these comments to the ONC in connection with the proposed TEFv2 and welcomes further dialogue with ONC on ways that Collective may be helpful in addressing policies and practices that promote sharing of EHI for the benefit of patients nationally. Please do not hesitate to contact us if we may be of any additional assistance.

Sincerely,

DocuSigned by:  
  
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