FAST

(FHIR AT SCALE TASK FORCE)

Directory, Versions and Scale Tiger Team

FAST Antitrust Notice

The ONC FHIR At Scale Task Force (Hereinafter "*FAST*") is committed to full compliance with existing federal and state antitrust laws.

All members involved in the Task Force effort, including its advisory groups, will comply with all applicable antitrust laws during the course of their activities. During Task Force meetings and other associated activities, including all informal or social discussions, each member shall refrain from discussing or exchanging competitively sensitive information with any other member. Such information includes, but may not be limited to:

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- Any other competitively sensitive information that is proprietary to a member company

If you have any specific questions or concerns, seek guidance from your own legal counsel.

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Agenda – March 7,2019

1. Antitrust statement
2. Welcome
   - Rebranding note: P2 is now *FAST* (*FHIR At Scale Taskforce*)
3. Deliverables
   1. Issues: Initial review 2/28. **Today's discussion will reframe into Issue Statements**
   2. Industry efforts
   3. Regulatory Barriers: **Introduce today**
4. Wrap Up

Please note that Tiger Team calls are recorded in support of summary creation and will not be publicly posted

Tiger Team Logistics

- Standing meeting: Thursday's 1 to 2 pm eastern
  - Calls recorded to aid meeting summary creation, but not posted
- *FAST* Project Page - Confluence:
  - https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Directory%2C+Versions+and+Scale+Tiger+Team
  - Public facing documents storage
- Slack:
  - https://dvstt.slack.com/messages/CBWQ10Y4U/
  - Messaging / team work zone

Defining Deliverables

- Alignment with *FAST* Tiger Team Direction
- DVS TT Activity List (see next slide)
- By end of March goal to complete items 1, 2, and 3

1. Clear definition of issues we have discussed and defined (D, V, S) *(bob & alix)*
2. Concise summary of industry efforts (who and what they are doing) *(patrick)*
    a. Provide evaluation of pro's and con's of solutions reviewed (example – Carequality, DirectTrust, etc.) and if they have a role moving forward with D, V, S scope
3. Define regulatory barriers that exist currently and impact *(bob & alix)*
4. Define/propose standards efforts, regulatory efforts, and timelines, for future state
5. In conjunction with Patrick and Paul, define a future state and preferred technical solution
6. To evaluate new regulatory efforts by ONC/CMS NPRMs and NCVHS
7. Present findings to members of Steering Committee for feedback, as appropriate
8. Identify "solutions" that would benefit from an industry driven review
9. Propose industry leaders review findings, evaluate approach, propose final solution (architectural design pattern + standards)

Issues: Versioning

How do we manage multiple versions of FHIR endpoints and FHIR artifacts?

- Currently multiple versions of FHIR in production
  - Guidelines for the number of versions to be recognized/supported
- Regulation supports adoption of new versions ad hoc
- FHIR will continue to evolve for foreseeable future
  - Framework capacity to keep pace with HL7 FHIR evolution
  - Backward compatibility goal recognizing challenges exists
  - Industry use of different versions and interplay with capability statements
- Single organization will have information provided on one or more patients from different versions of FHIR
- Breaking changes between versions restrict ability to translate between versions

Issues: Identifying FHIR Endpoints & Services –

How can a provider or payer identify appropriate FHIR endpoints and the specific "services" they support for ~~P-P~~ exchanges in a scalable fashion?

- Balancing efficiency and trust
  - Point to point vs. brokered endpoint/utility to get access to desired endpoint
  - Provider directory quality for reliable endpoint URI identification and capability statement / payload receipt capability. Viability of NPPES usage as proposed.
  - Need for pre-registration expected by some, but not others (private vs. public)
  - Trust framework (authorization and authentication aspects; contractual agreements vs. principles to follow)
  - Trusted source for information and accepted ecosystem work products
- Patient identification and reconciliation
  - Is not Directory issue per se and anticipate Identify TT to tackle lack of UPI and workaround needed to have confidence in patient matching
  - Scale challenge: Where is all the data for a given patient & where do I go look for it

Issues: Identifying FHIR Endpoints & Services (2)

- Scope and breadth of Directory information
- Ongoing maintenance of Directory
- Interplay with Testing/Cert Tiger Team scope of work
- Questions unresolved and needing further TT discussion (future state convo?):
  - Who has the right to know an end point exists?
  - Who are authorized users of the directory?
  - How is directory access granted and managed?
  - What are the data elements in the directory?
  - How is information populated and maintained?
  - What level of automation is needed for populating directory contents?
  - Is directory information to be verified by external entity?
  - What is the availability of the directory (up-time/SLAs)?
  - What are the audit trail requirements of the directory?

Issues: Scaling

How do we take FHIR based exchanges that work with a limited number of endpoints and/or participants (e.g. pilots) to a national scale (tens of thousands of endpoints and millions of providers)?

- Design scope to accommodate mixed models: spoke/hub, direct connections (point to point), and regionally interconnected spoke/hub
- Real time validation of data being feasible
- Performance requirements (SLAs for availability and response times) for direct connections and spoke/hub models
- Where is all the data for a given patient & where do I go look for it
- Is there a maximum to the scaling that needs to be considered? Patients, Providers, Devices and the number of daily exchanges that will be done in FHIR and over what timeframe (next decade).

Regulatory Barriers

What regulations are standing in our way

HIPAA minimum necessary

- Impossible to implement or enforce (requires requester to understand what sender has and requires sender to understand what a requester needs) – most commonly it is ignored and the entire record is exchanged
- Creates significant barrier in real-time access to records
- Need solution where requester is responsible for limiting use of data to declared purpose (similar to BAA)

HIPAA mandatory transactions

- Limiting transactions to the X12 standard stifles innovation and real-time exchange of information for prior-authorization
- Need to change from regulation that is floor and ceiling to a floor only (must support, but can also provider alternative between trading partners)

Patient Identifiers

- Inability to have a single identifier for a patient causes significant cost and potential liability
- Need ability to assign and communicate a single identifier for use by all providers and payers (e.g. Medicare ID)

Data Blocking (restricted access to data or unreasonable cost of access)

- Inability or excessive cost to share information to support TPO creates an undue burden on both providers and payers
- Need requirement to make provider/payer information available based on need and limit associated cost

Deliverables and Related Regulation (examples)

What should we expect from the Tiger Teams as they create solutions to address the technical barriers

Identify

- Define a standard for patient matching to be implemented by all payers and providers (assuming cannot implement one patient ID
- **Law to limit liability if the standard is used and an error occurs**
- Possible use of a payer generated identifier incorporated in all EHR's records to allow unambiguous access for allowed purposes

Security

- Standard scalable process to identify a payer, provider or patient that meets all required standards for identity
- **Law to allow/required use of the identity process with limitation on liability if error occurs.**
- Standard for defining sensitive data and patients right to restrict / grant access to sensitive data or all of record
- **Allowing additional limitations on data access may compromise patient care and should only be accompanied by limitations on liability**

Directory

- Name Validated Directory Work from ONC as standard
- **Regulations (or extension of 21st Century Cures Act) to allow CMS to build, maintain and distribute validated data**
- **Initial "carrot" by requiring anyone asking for supported data to get it from the directory for participating provider**
- **Eventual "stick" where non-participation will result in non-eligibility to participate in Medicare or Medicaid programs**