

***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:

- Price, premiums, or reimbursement charged or paid for products or services
- Allocation of customers, enrollees, sales territories, sales of any products or contracts with providers
- 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.

Members should not bring confidential information or intellectual property (hereinafter “Intellectual Property”) owned by their respective member companies into Task Force meetings. To the extent such Intellectual Property is shared with the Task Force that shall not be construed as a waiver of member company’s rights to, or ownership in, the Intellectual Property.

# Agenda – April 11, 2019

1. Antitrust statement
2. Welcome
3. Tiger Team Process and Deliverables
  1. Issues/Barriers
  2. Industry efforts: Continue Review of Initial Draft from Patrick
  3. Regulatory Barriers
  4. **Submission of Issues/Barriers, Regulatory, Industry**
  5. Proposed Rules: Continue NPRM discussions
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://oncprojecttracking.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/early April goal to complete items 1, 2, and 3

1. Clear definition of issues we have discussed and defined (D, V, S) (*bob & alix*) (*Completed 3/14*)
2. Concise summary of industry efforts (who and what they are doing) (*patrick*) (*Started 3/28; continue review & discussion 4/4*)
  - 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*) (*Completed 3/28*)
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 (*April focus*)
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?*

1. Currently multiple versions of FHIR in production
  - Guidelines for the number of versions to be recognized/supported
2. Regulation supports adoption of new versions ad hoc
3. 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
4. Single organization will have information provided on one or more patients from different versions of FHIR
5. Breaking changes between versions restrict ability to translate between versions, expect incompatibilities to decrease overtime as more FHIR resources become normative
6. Version issues are not limited to releases of the FHIR core artifacts, but include extensions, profiles and implementation guides
7. Issues related to implementation of versions should be considered by the testing and certification tiger team (and will not be addressed by DVS TT)
8. FHIR versioning of RESTful APIs may differ from general industry definitions

# 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?*

1. Ability to identify a FHIR endpoint (server w/ capability statement) or other FHIR enabled-service endpoint associated with a specific organization
2. Ability to identify trust framework and/or authentication requirements associated with a FHIR endpoint
3. Ability to identify the version(s) of FHIR supported at a specific FHIR endpoint
4. Ability to clearly define in and understand supported services
5. Ability for keep Directory information up-to-date with actual end point capabilities
6. Ability to capture/represent testing/certification information
7. Ability to keep endpoint and service related information current
8. Ability to restrict to access to end point details



# 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)?*

1. Multiple current models for interoperability between providers and payers create challenges in adopting standards for scaling FHIR
  - Mixed models: spoke/hub, direct connections (point to point), and regionally interconnected spoke/hub
2. Real-time interactions involving FHIR require predictable availability and response times; Scaling real-time transactions requires infrastructure that may not be currently available in existing intermediaries
  - SLAs for availability and response times for direct connections and spoke/hub models
  - For example, business impacts from down-nodes. Real time validation of data being feasible
3. Lack of unique patient identifier and the probabilistic nature of patient matching creates an environment in which positive identification of a patient and association of their records is problematic
4. There is no current process for universally determining all endpoints that have information for a specific patient
5. Increase availability of real-time transactions between payers, providers, patients and third party services will exponentially increase transaction volumes; There is currently no reasonable model to predict the volume of FHIR based transactions as FHIR is adopted broadly in the eco-system
  - 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) will continue to evolve exponentially.

# Regulatory Barriers – *A Global View, Not Just DVS*

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. 3/14: Eliminate need for “I’ll know it when I see it” by creating rules that can be computer processed. BAA (HIPAA related solution) could be to declare at time of request to use data for specific request (could overcome lack of data structure for all elements and how its captured)
- Creates significant barrier in real-time access to records (complicated by data entry/storage choices)
- Need solution where requester is responsible for limiting use of data to declared purpose (similar to BAA)

## HIPAA mandatory transactions [3/14: NPRM interplay – move to new version if it doesn’t break; backward compatibility]

- 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** [3/28: Probabilistic necessity today; NPRM interplay with RFI; Lack of Individual Identifier creates risk and increases costs and likely false sense of identity protections; Uses of data and related protections; - TT believes single patient identifier is important as we already have in some areas (medicare, Medicaid, dod, va)]

- 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)** [3/14: NPRM addressing. 3/28: Area of concern beyond NPRM policy benefit relates to charge and other indirect cost aspects related to build out and ongoing exchange; troubling gap potential in NPRM is complicated web of connections and who can charges fees: *data holder and intermediary/CH cost aspects*. Reality of tx volumes increases 10 to 100 fold over next 5 to 7 years due to clinical exchange “dialogue” among providers and payers (need to craft some text around this.. )

- 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.

3/28: Red text is regulatory implications of possible solutions – meaning we are ahead of ourselves as we define our solutions.

## Identity

- 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 21<sup>st</sup> 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**

## Consent (requested addition from 3/21 meeting notes)

# Industry Summation – Initial Draft Spreadsheet

1	Landscape Item	Dimension Considered	Description	Segment	Relevant Services	Synergies	Tiger Team Cross Pollination	Client Examples
	Apple	Scale	Leading consumer hardware, software, app organization	Consumer	<ul style="list-style-type: none"> <li>- Massive scale</li> <li>- FHIR consumer mediated apps, including payer/provider</li> <li>- Innovation platform</li> </ul> <p>Standards Supported</p> <ul style="list-style-type: none"> <li>- FHIR STU2</li> </ul> <p>Exchange Methods</p> <ul style="list-style-type: none"> <li>- FHIR</li> </ul> <p>Content Standards</p> <ul style="list-style-type: none"> <li>- HL7</li> </ul> <p>Trust Framework</p> <ul style="list-style-type: none"> <li>- Consumer mediated</li> <li>- After onboarding there is a directory service (closed interchange community)</li> </ul>	<ul style="list-style-type: none"> <li>- Expected to be leader on consumer mediation</li> <li>- Strong history of leading spaces in which they enter</li> <li>- Strong history of revolutionary app development</li> <li>- Considered to be trusted source by consumers</li> <li>- Onboard FHIR enabled providers/EHRs</li> </ul>		<ul style="list-style-type: none"> <li>- Billions of consumers</li> </ul>
2	Availity	Directory/Scale/Versioning	Existing health care clearing house, provider/payer connectivity framework, revenue cycle management organization.	Health Care	<p>Standards Supported</p> <ul style="list-style-type: none"> <li>- X12</li> <li>- Partial FHIR</li> <li>- SOAP</li> <li>- REST</li> <li>- Batch</li> <li>- Partial HL7 v2 and v3</li> </ul> <p>Exchange Methods</p> <ul style="list-style-type: none"> <li>- Soap</li> <li>- REST</li> <li>- Batch</li> <li>- Portal</li> </ul> <p>Trust Frameworks</p> <ul style="list-style-type: none"> <li>- Proprietary</li> </ul>	<ul style="list-style-type: none"> <li>- Architecture runs at scale</li> <li>- Foundation of provider directory</li> <li>- Foundations of provider data management</li> <li>- Payer agnosticism</li> <li>- Establish &amp; trusted intermediary</li> <li>- Basic endpoint determination</li> <li>- Onboarding services</li> </ul>	Exchange	<ul style="list-style-type: none"> <li>- Most payers</li> <li>- Most providers</li> </ul>
3	Commonwell	Directory/Scale	One of the two existing major networks used by EMR vendors	Health Care	<p>Standards Supported</p> <ul style="list-style-type: none"> <li>- IHE Profiles</li> <li>- PIX</li> <li>- XCA/XDS.b</li> <li>- XUA</li> </ul>	<ul style="list-style-type: none"> <li>- Person enrollment</li> <li>- Record location</li> <li>- Patient identification &amp; linking</li> <li>- Query and retrieval</li> <li>- Directory services</li> </ul>	Exchange	EMR