2022

Annual Meeting

GRAND HYATT WASHINGTON

Understanding TEFCA

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Topics

1. What is TEFCA
2. How an eHealth Exchange QHIN might look
3. Questions & Answers

TEFCA Statutory Authority & Elements

Section 4003(b) of the 21st Century Cures Act requires the Office of the National Coordinator to "develop or support a **trusted exchange framework** for **trust policies and practices** and for a **common agreement** for exchange between health information networks," (emphasis added).

Elements:

TEFCA Goals

GOAL 1
Establish a floor of universal interoperability across the country

GOAL 2
Create simplified nationwide connectivity

GOAL 3
Provide the infrastructure to allow individuals to gather their data

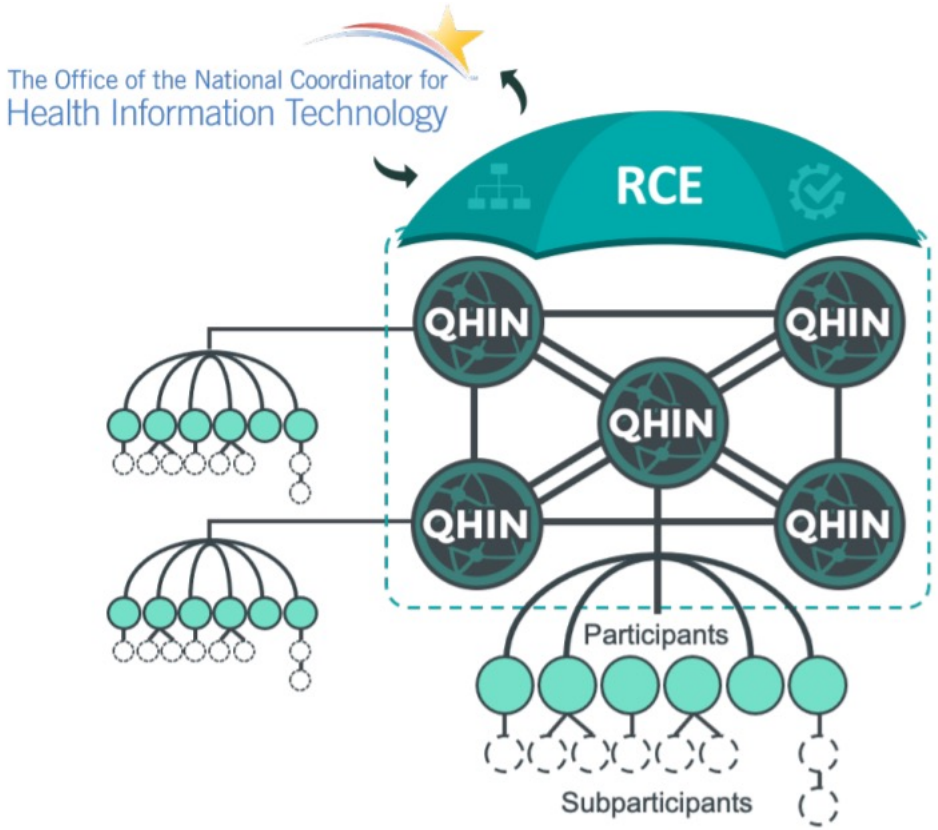
Simplified connectivity for individuals, health care providers, health plans, public health agencies, and other stakeholders.

How will TEFCA Work?

Common Agreement

- QHIN Technical Framework
- Standard Operating Procedures

- FHIR Roadmap



ONC defines overall policy and certain governance requirements.

RCE provides oversight and governing approach for QHINs.

Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

Each QHIN connects Participants, which connect Subparticipants.

What is the Common Agreement?

- The **Common Agreement** establishes the infrastructure model and governing approach for users in different health information networks to securely share clinical information with each other.
- The Common Agreement is a legal contract that both the RCE signs and a health information network (or other entity) signs.
  - The latter becomes a Qualified Health Information Network (QHIN) once fully onboarded and designated by the RCE.
- Some provisions of the Common Agreement will flow down to entities in a QHIN's network via other agreements.
- The Common Agreement incorporates the QHIN Technical Framework and the Standard Operating Procedures (SOPs).

Common Agreement – Required Flow-Downs Overview

- The Common Agreement identifies specific Required Flow-Downs that QHINs must pass down to their Participants.
- The Required Flow-Downs also include an obligation on the Participants to further flow down these terms to their Subparticipants, and so on down the chain.
- The following slide lists the Required Flow-Downs that eHealth Exchange would have to flow down to any eHealth Exchange Participant that decides to exchange via the TEFCA, and that those Participants would have to flow down to any of their Subparticipants that decide to exchange via the TEFCA.
- The means by which the eHealth Exchange would flow-down these terms to its Participants would be through a TEFCA-specific Addendum.

Common Agreement – Required Flow-Downs

- 6.1 Cooperation
- 6.2.1 Prohibition Against Exclusivity
- 6.2.2 No Discriminatory Limits on Exchange of TI
- 7.1 Confidential Information
- 8.2 Utilization of the RCE Directory Service
- 9.2 Uses
- 9.3 Disclosures
- 9.4 Responses
- 9.5 Special Legal Requirements
- 10 Individual Access Services[1]
- 11 Privacy
- 12.1.4 Participants and Subparticipants [Security]
- 12.2 TI Outside the United States
- 13.1 Compliance with Applicable Law and the Framework Agreements
- 13.2.2 Responsibility of Signatory
- 13.3 Flow-Down Rights to Suspend
- 13.4 Survival for Participants and Subparticipants

Standard Operating Procedures (SOPs)

Final:

1. Advisory Groups SOP
2. Conflicts of Interest SOP
3. Dispute Resolution Process SOP
4. TEFCA Governing Council SOP
5. Exchange Purposes SOP
6. IAS Exchange Purpose Implementation SOP
7. Means To Demonstrate U.S. Ownership/Control of a QHIN SOP
8. QHIN Cybersecurity Coverage SOP
9. QHIN Onboarding & Designation SOP
10. QHIN Security Requirements for the Protection of TEFCA Information (Rev.1) SOP
11. TEFCA Governing Council SOP
12. Transitional Council SOP
13. Types of Entities That Can Be a Participant or Subparticipant in TEFCA SOP

Coming Soon:

14. SOP: Individual Access Service (IAS) Provider Privacy and Security Notice
15. SOP: Participant and Subparticipant Security DRAFT released 12-05-2022 with comment deadline January 13, 2023
16. SOP: Other Security Incidents and Reportable Events
17. SOP: Payment and Health Care Operations Exchange Purpose Implementation
18. SOP: Public Health Exchange Purpose Implementation
19. SOP: Government Benefits Determination Exchange Purpose Implementation
20. SOP: Suspensions Process
21. SOP: Successor RCE & Transition

TEFCA Governance

Transitional Council

- The first 10 Designated QHINs from the first application period appoint one rep
  - If there are more than 10, then each QHIN may appoint 1
  - If there are fewer than 10, then each QHIN still appoints one but the total number of QHIN reps is less
- Each of these Designated QHINs shall appoint 1 individual from its Participants or Subparticipants
- The RCE has one rep and will facilitate the Transitional Council work
- 12-month life span beginning when first "group" of QHINs are "Designated" by the RCE
- The Transitional Council will grapple with "first impression" governance issues as TEFCA gets off the ground

TEFCA Governance

Governing Council

- Replaces the Transitional Council after 12 months and is the “permanent” governing body
- Up to 21 members
  - QHIN Caucus selects up to 10 individuals affiliated with a QHIN
  - Participant/Subparticipant Caucus selects up to 10 individuals affiliated with a Participant/Subparticipant
  - The RCE designates one member
- Leadership-2 co-chairs, one from the QHIN members and one from the Participant/Subparticipant members
- Quorum is 2/3 of QHIN members and 2/3 of Participant/Subparticipant members
- Once a quorum is established, a simple majority of all GC members will constitute approval

TEFCA Governance

Caucuses

- Each QHIN will be a member of the QHIN Caucus
- Each QHIN has the right to appoint up to 3 individuals who are affiliated with its Participants and Subparticipants to serve on the Participant/Subparticipant Caucus
- These Caucuses each select 10 members of the Governing Council
- eHealth Exchange is developing a process for how it will facilitate Participants/Subparticipants to serve on the Participant/Subparticipant Caucus

QHIN Technical Framework

- The QTF articulates the "technical and functional requirements for interoperability among QHINs, including specification of the standards that QHINs must implement to enable QHIN-to-QHIN exchange of health information."
- The QTF also sets forth the "high-level functional requirements" that QHINs must support.
- While the QTF is largely focused on the technical and functional requirements of ***QHINs***, there are technical requirements applicable to Query/Message Sources and to Responding Sources.

What would an eHealth Exchange QHIN Look Like?

Participant Opt-out Process Summary

1. If HHS ONC's Recognized Coordinating Entity (RCE) approves eHealth Exchange's QHIN application, the Coordinating Committee will direct eHealth Exchange staff to notify Participants they have the right to opt-out of TEFCA exchange via the eHealth Exchange QHIN. This notification will include :
    1. The Common Agreement
    2. eHealth Exchange TEFCA Terms & Conditions
    3. eHealth Exchange TEFCA protocols
    4. Dates for TEFCA education sessions
    5. A deadline of at least 60 days (tbd by the Coordinating Committee) to **opt-out** of TEFCA exchange via the eHealth Exchange QHIN, or be deemed to be participating in the eHealth Exchange QHIN and bound by eHealth Exchange's TEFCA terms.

2. eHealth Exchange staff will apprise the Coordinating Committee of any Participant concerns or comments submitted.

Just as when eHealth Exchange joined Carequality, eHealth Exchange will make best efforts to ensure Participants who do not opt-out truly intend to exchange via eHealth Exchange's QHIN.

eHealth Exchange TEFCA Terms & Conditions

- These incorporate the ONC required flow-downs that Steve talked about earlier
- We created these Terms and Conditions to help eHealth Exchange Participants understand what the flow downs mean for them and their Subparticipants
- The Terms and Conditions provide Participants with a way to approach complying with the required flow-downs, every Participant that does not opt-out of TEFCA will be required to comply with these Terms and Conditions without any edits just like the DURSA

eHealth Exchange TEFCA Protocols

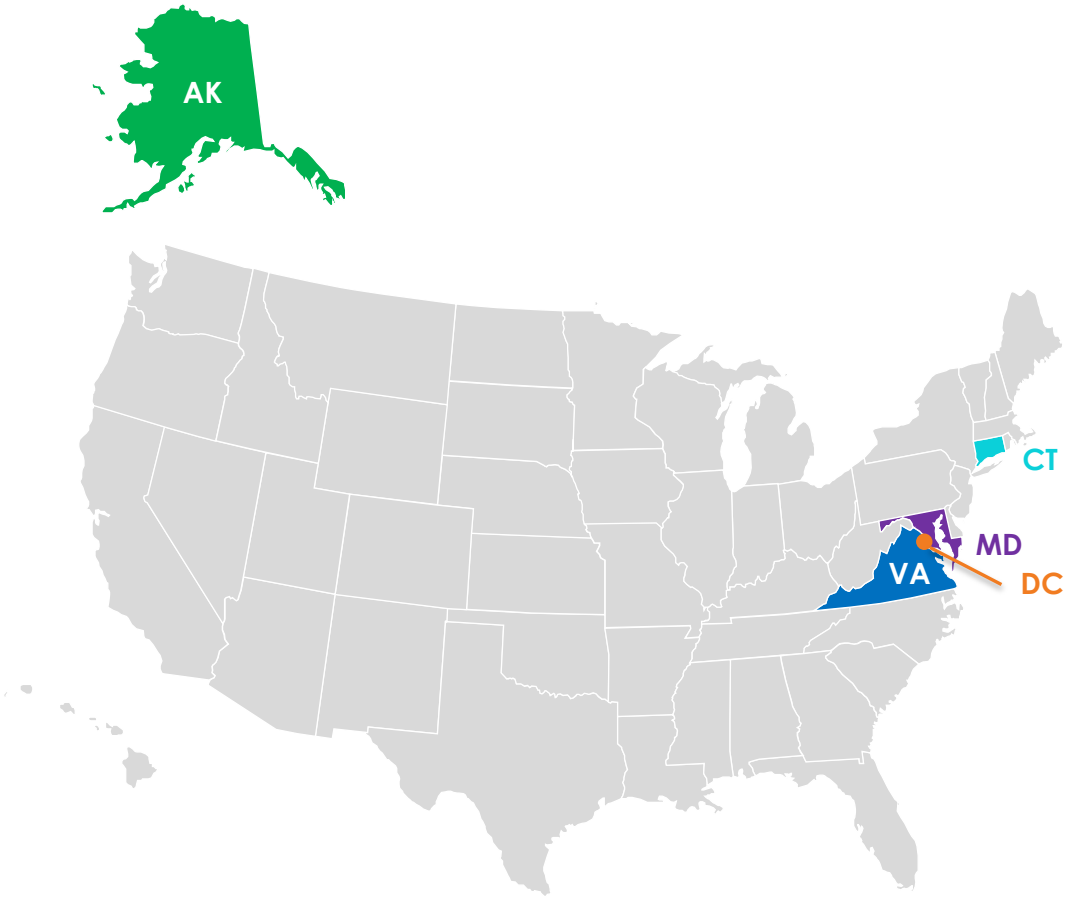
- We want our Participants that do not opt-out of TEFCA to be able to comply with the requirements without having to spend a lot of time and money trying to unpack the Common Agreement and SOPs
- The purpose of these Protocols is to provide additional details about the required flow-downs and guidance on what Participants need to do to comply with the flow-downs
- Likely Initial Protocols:
    1. eHealth Exchange TEFCA Governance Protocol
    2. eHealth Exchange TEFCA Change Management Protocol draft
    3. eHealth Exchange TEFCA Security Incident Protocol draft

Geo-Location - Routing Other QHINs' Queries to eHealth Exchange QHIN Participants

Tradeoffs for Optimal Patient Matching

While no RLS solution is perfect, we've mathematically proven a geo-location approach which balances tradeoffs to optimize the number of successful patient matches with minimal queries.

- **Goal 1:** *Expand* the population of candidate patient matches (with the minimum number of queries).
- **Goal 2:** *Reduce* the population to query to decrease the chance of **false positives** which can:
  - corrupt patient records
  - return zero patient matches if >1 match



	Potential eHealth Exchange QHIN Participants Receiving Queries from other QHINs		
	Alaska HIE	**Maryland HIE**	**Virginia HIE**
Periodically reset RLS scope based on how much care QHIN Participants' provide for out of area patients (# out of area patient addresses)	99% of Alaska's records are for Alaska patients	• 98% of Maryland's records are for Maryland patients • 1% patients have Virginia address	99% of their records are for Virginia patients
Scenario 1: If another QHIN requests data for patient with current Alaska address & no past addresses, query:	Yes	No	No
Scenario 2: If another QHIN requests data for patient with a current Maryland address & no past addresses, query:	No	Yes	Yes (because a significant percentage (1%) of Virginia patients receive care in Maryland
Scenario 3: If another QHIN requests data for patient with a current Virginia address & past Alaska address, query:	Yes (because previous address)	Yes (because a significant percentage (1%) of Virginia patients receive care in Maryland	Yes (because current address)
Scenario 4: If another QHIN requests data for patient with a current New Mexico (out of service area) address & no past addresses, query:	No, because this QHIN Participant doesn't have much **NM** data.	No, because this QHIN Participant doesn't have much **NM** data.	No, because this QHIN Participant doesn't have much **NM** data

Major Technical Differences eHealth Exchange QHIN Participants Must Support

1. Adopt **USDCI v1** data classes and elements
2. Adhere to the **Concise Consolidated CDA** 1.1 Specification
3. Adhere to **Postal Address Standards**
4. Adopt **IHE ITI Technical Framework Revisions 17.0** (versus Revision 8.0)
5. Accept **aggregated XCPD responses**
6. Various requirements such Purpose Of Use values, different consent attribute structure, sub-participant directory entries and detailed reporting, onboarding log submissions, specific test patients, and quarterly reporting.

QHIN Required Responses

QHIN Participants and Sub-Participants must:

1. Respond to **Treatment** queries (effective immediately)
2. Respond to **Individuals'** requests (effective March 16, 2023 based on the IAS SOP publication on September 16, 2022)
3. Respond to **Government Benefits Determination** queries (effective date tbd)
4. Respond to **Healthcare Operations** (HCO) queries (effective date tbd)
5. Respond to **Payment** queries (effective date tbd)
6. Respond to **Public Health** queries (effective date tbd)
7. Adhere to the TEFCA **FHIR Roadmap** (effective date tbd)

Questions & Answers

Appendix – Additional Slides

QHIN Participant & Sub-Participant Governance Inclusion

1. Transitional Council (1st Year) – 1 QHIN Participant or Sub-participant

2. Governance Council (month 13) – QHIN Participant caucus selects up to 10 QHIN Participants or Sub-Participants from among all QHINs

New Network Agreements & OPP-10

- **Section 4.03(m) of the DURSA** specifically grants the Coordinating Committee the authority to enter into agreements "to broaden access to data to enhance connectivity across platforms and networks" in accordance with the Operating Policies and Procedures.
- **OPP-10 outlines the process around entering into such new agreements.**
- "This process includes notice to the Participants that a new data sharing agreement may soon be entered into, an opportunity to review the data sharing agreement and any applicable flow-down provisions, and determine whether the Participant is required to opt-out and time to notify the Coordinating Committee if the Participant does opt-out."
- "For those Participants that do not opt out, they will be subject to the terms of the network agreement that are required to be flowed down to that network's participants. … The eHealth Exchange Coordinating Committee must identify the terms that the network requires to be flowed down to eHealth Exchange Participants."

OPP-10 Overview of Notice & Opt-Out Process

- eHealth Exchange staff must notify all Participants in writing that the Coordinating Committee **anticipates*** entering into a new data sharing agreement as authorized by Section 4.03(m) of the DURSA.
  - Participants must be afforded at least 60 days from the date of the notice to decide whether to opt-out of the terms of the new network. Therefore, notice must precede the effectiveness of the new agreement, which is why this is phrased in terms of providing notice that the CC *anticipates* entering into such an agreement.
  - "Prior notification also seeks to ensure that the Coordinating Committee will be fully apprised of any concerns or comments Participants may have prior to entering into a new data sharing arrangement."
- The notification must include a summary of the new agreement, a copy of the agreement (in this case, the Common Agreement), and any applicable flow-down terms with which the Participant may be obligated to comply (i.e., at a minimum, those terms identified in the CA as "Required Flow-Down(s)").

OPP-10 Overview of Notice & Opt-Out Process (Cont.)

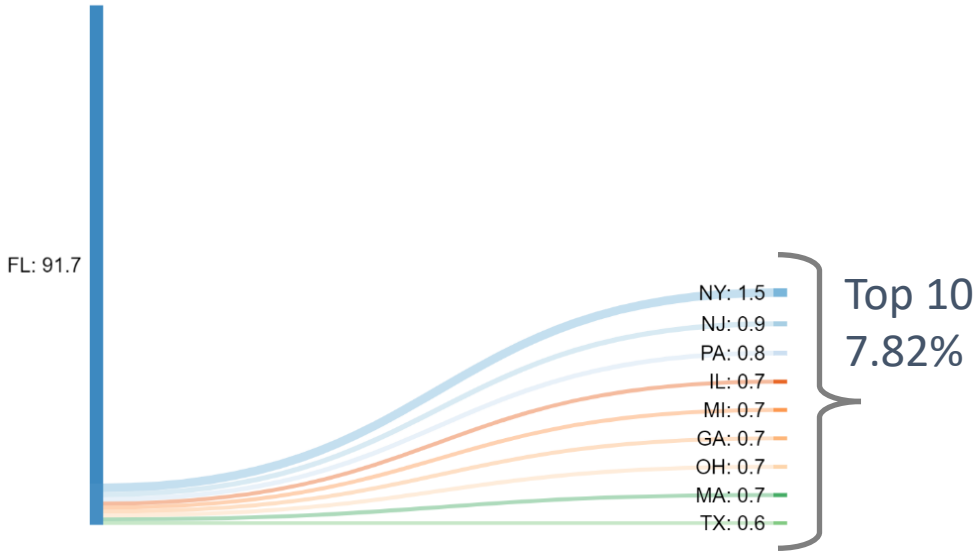
- If a Participant does not affirmatively opt-out within 60 days of the notice, then the Participant is deemed to be participating in the new network.
- OPP-10 states that eHealth Exchange Staff will be available to answer questions from Participants about the flow-down terms and may conduct webinars to educate Participants on such terms.
- Section 12.05 of the DURSA states, in relevant part, that a Participant "may choose to opt-out of participation in these [new] platforms or networks for any reason. … At any time, a Participant may reverse its decision to opt-out."
- Finally, OPP-10 tasks the eHealth Exchange Executive Director with reviewing any opt-out notices that are submitted within the 60-day period and discussing them with both the CC and the Participant in an effort to address the concerns identified in the opt-out notice.

#	Factor	CommonWell (Centralized)	Epic (Federated)	VA (Federated)	eHealth Exchange (Federated)
	Approach	ADT feeds to Change MPI; a mixture of auto/manual linking	Geospatial (zip+50mi) plus "link-forwarding"	XCPD "mega-broadcast" query of all node	Geospatial based on known state coverage
1	# of Queries / Performance	1	20-50	300	5-10 (1-5 state HIE(s), DaVita, etc.)
2	Authoritative (all nodes)?	No, due to manual correlation step	Almost (due to link-forwarding)	Yes	Almost (due to state HIE RLS's)
3	Authoritative (practical)	No, due to manual correlation step			
4	Measured Effectiveness	~80%	~99%	~100%	~99%
5	Regional effectiveness	~80%	~99%	~100%	~99%
6	State effectiveness	~80%	~99%	~100%	~99%
7	Relo/snowbird effectiveness	~80%	~99% (due to link forwarding)	~100%	~99% (due to historical addresses)
8	ED out of state	~80%	~99% (due to link forwarding)	~100%	~99% (due to historical addresses)
9	PCP after ED out of state	~80%	~99% (due to link forwarding)	~100%	~99% (assumes PCDH)
10	Cyber risk	Major risk	Federated – no centralized data	Federated – no centralized data	Federated – no centralized data
	Summary	CW's model has shortcomings: • Match attributes: Name, DoB, Address (not SSN, etc). • Match set high since national • Match can return only 1 match • A mix of manual and auto-link • Not always full historical load • Algo does not use newer techniques (e.g. referential) • Examples: Dignity-Sutter (3-5%), Ai and MX to CW (80%)	Epic has been successful with CareEverywhere for many years. Link-forwarding creates a unique additional solution for matching (as does MyChart Central, Payer Platform, etc).	This approach works and allows for per-site matching (to minimize the population size to query). One criticism is load and efficiency (but sending ADTs to centralized RLS is also not efficient).	Assuming HIE's join TEFCA: • HIE's are federated RLSs • HIE's know the %State in MPIs • eHeX filters non-state queries • Data showed this to be >99% • PCDH keeps regional HIEs whole

None of the options are perfect. However, eHealth Exchange and Epic's geo-spatial approaches balance match rates with the risks of false positives and cyber attack.

The federated approaches are proven, allow for different consent and matching policies, and enable an incremental roll-out.

MPI – State Histogram Example



Top 10:
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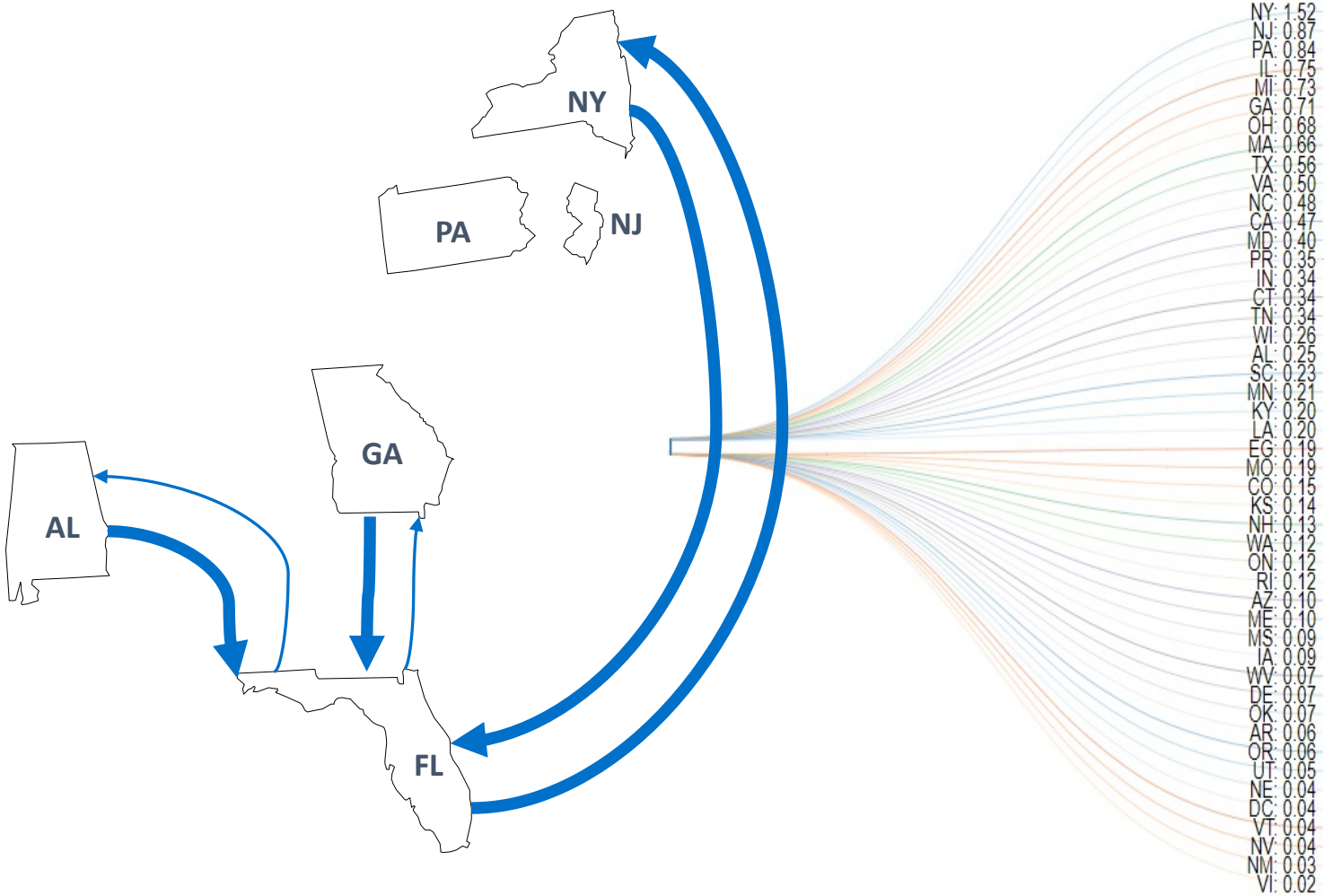
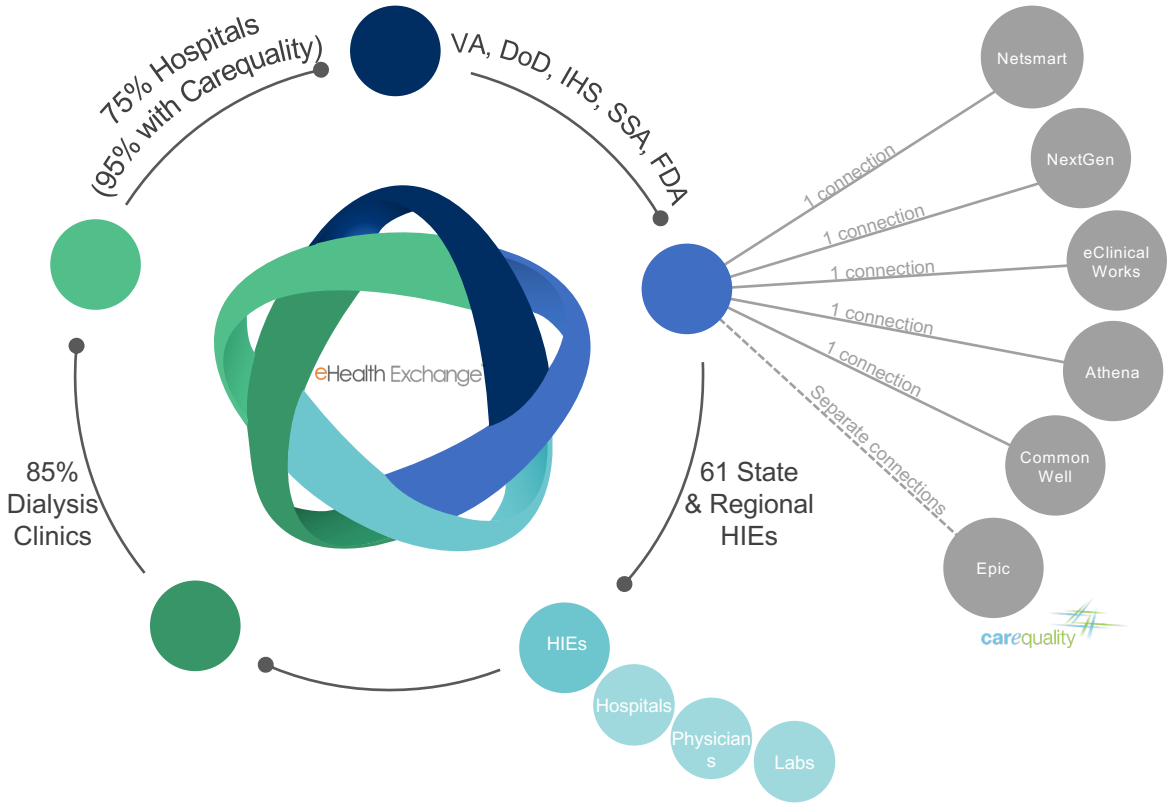


Carequality



TEFCA