Interoperability Matters
Public Advisory Forum

12/16/2019
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The Sequoia Project Team

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Mark Segal, Digital Health Policy Advisors

Dawn Van Dyke, Director, Marketing Communications

Mariann Yeager, CEO
Agenda

• Review Agenda
• Information Blocking Workgroup
  – Phase II Updates [Advise]
• New Interoperability Matters project [Advise]
• TEFCA Update: RCE Updates [Inform]
• Public Advisory Forum [Inform]
Information Blocking Workgroup
Phase 2
Workgroup Representatives

**Associations and Orgs - health IT community**
- Anne Kimbol, HITRUST Alliance
- Mari Greenberger, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust

**Consumers**
- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciitizen

**Consultant**
- Brian Ahier, MITRE Corporation

**Federal Government**
- Steve Bounds, SSA

**Health Information Networks and Service Providers**
- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange
- Paul Uhrig, Surescripts, Co-Chair

**Healthcare Provider**
- David Camitta, CommonSpirit, Co-Chair
- Eric Liederman, Kaiser Permanente
- Matt Reid, AMA
- Mari Savickis, CHIME

**Legal, Technology, Standards, and Policy Subject Matter Experts**
- Jodi Daniel, Crowell & Moring, LLP
- Josh Mandel, Microsoft
- Micky Tripathi, MaEHC

**Payers**
- Nancy Beavin, Humana
- Danielle Lloyd, AHIP
- Matthew Schuller, BCBSA

**Public Health**
- John Loonsk, APHL

**Vendors**
- Aashima Gupta, Google
- Cherie Holmes-Henry, EHRA / NEXTGEN
- Rob Klootwyk, Epic
- Josh Mast, Cerner

**Informatics**
- Doug Fridsma, AMIA

**Safety Net Providers / Service Provider**
- Jennifer Stoll, OCHIN

**Release of Information Company**
- Rita Bowen, MROCorp

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Information Blocking Workgroup: Purpose

- Provide input into Sequoia comments to ONC on proposed rule
- Identify practical, implementation-level implications of proposed and final information blocking rules, which may or may not be consensus positions
- Facilitate ongoing discussions to clarify information blocking policies and considerations prior to and after the Final Rule
Information Blocking Workgroup: Agenda—Phase 2

Overall approach: Focus on implementation and compliance implications of ONC proposed rule elements and likely outcomes. Not relitigating comments.

- Meeting 1 (6/20) Review comments submitted and proposed workplan
  - No July Call
- Meeting 2 (8/2) HIE/HIN and Other Key Definitions
- Joint Workgroup & Leadership Council (8/21) – In-person and virtual
- Meeting 3 (9/13) Information Blocking Practices
- Meeting 4 (10/11) Recovering Costs/RAND Licensing
- Meeting 5 (11/8) Compliance Plans
- Meeting 6 (12/13) Compliance Plans (cont.), Implementation Plans and Phase 2 Review

Deliverable: Summary of Phase 2: Guidance to the Community and Implementation Feedback to ONC
Phase 2 Topics for Deliverable: Discussion Summary
ONC and CMS Rules in Final OMB Clearance

AGENCY: HHS-CMS
TITLE: Interoperability and Patient Access (CMS-9115-F)
STAGE: Final Rule
RECEIVED DATE: 09/26/2019
RIN: 0938-ATT9
ECONOMICALLY SIGNIFICANT: Yes
LEGAL DEADLINE: Statutory
Status: Pending Review

AGENCY: HHS-ONC
TITLE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program
STAGE: Final Rule
RECEIVED DATE: 10/28/2019
RIN: 0955-AA01
ECONOMICALLY SIGNIFICANT: Yes
LEGAL DEADLINE: None
Status: Pending Review
HIE/HIN and Other Key Definitions
Implementation & Compliance Implications/Needs

HIEs/HIN Definitions: HITAC Proposed Revisions

- Definitions too confusing, even for expert likely more confusing in actual practice
- Proposed revisions positive, but still concerns, especially with broad EHI definition
- HITAC proposed revised HIE definition clearer, category overlap removed
  - Unusual to be an HIE if not an HIN.
- Revised HIN definition improved but still too broad, continued use of “or” between criteria underscores broad definition
- Guidance essential for final definitions., including likely scenarios
- Essential to understand how definitions used by enforcement agencies, such as OIG, ONC, and CMS and whether they have consistent interpretations
- Definitions will be used in other regulations and policies, like TEFCA
- Some broad scope may not matter (e.g., an EHR Developer that is a HIN would have no additional enforcement exposure)
- But, a health plan, not an “actor,” could be an HIE or HIN and subject to regulations.
- Will take years for implications of definitions and other elements of enforcement to become clear, through cases and enforcement decisions
  - 25+ years for clarity around fraud and abuse/Stark/Anti-Kickback Statute/Federal False Claims Act enforcement
- Risk of paralysis in organizational decision-making from policy ambiguity; clarity in definitions essential
- Common theme: definition breadth and overlap has real and practical implications.
- Workgroup can provide tools and perspectives to help organizations deal with ambiguity
Implementation & Compliance Implications/Needs

HIEs/HIN definitions: Who might be unexpectedly included?

- **Provider organizations**, especially those in ACOs where data sharing essential;
- **Payers** (HIEs/HINs, even under HITAC revision, especially with focus on “agreements”);
- **“Individuals”** who “substantially influence” policies (e.g., HIM professionals, privacy officers);
- **Release-of-Information vendors**;
- **Interoperability and interface vendors** and any organization with “integration” in name or mission, for example:
  - Third party integrators working with health plans and providers
  - Companies providing technology and technology support for HIEs and HIT developers;
- **Clinical registries** (many need to use non-standard data elements and terms);
- **Companies that rely on remote data access** for their core functionality, such as analytics and clinical decision support vendors;
- **Standards Development Organizations** (SDOs) and other organizations that define policies and standards for the industry; and
- **Digital wellness vendors**
Implementation & Compliance Implications/Needs

HIEs/HIN Definitions

Exceptions

• Unclear which likely most relevant to broad HIE/HIN definitions

• Exceptions proposed by ONC because they promote a public interest/greater good, not to reduce actor burden and not as safe harbors

• Recent CMS interoperability proposed rule has detailed contractual requirements for health plans for interoperability but no exceptions, which plans may need

Provisions likely to be especially challenging or with unique in application to broadly defined HINs or HIEs

• Limits on non-standard technology

• Pricing requirements/exceptions

• Contracting rules (e.g., RAND terms)

• Documentation requirements – many organizations that may be included as HIEs and HINs are less experienced with compliance-related documentation requirements

• "Individuals" defined as HIEs or HINs
Implementation & Compliance Implications/Needs
Interoperability Elements and HIEs/HINs: Organizational Priorities

• Actors and potential actors should think about all issues associated with information blocking compliance
• Plan for the worst case
• Challenging to ensure that smaller clinician practices obtain needed compliance expertise and resources
  • Some clinician practices may be HIE or HINs
• Implementing certain exceptions will require organizational policies and procedures and need to integrate these into workflows
  • e.g., "minimum necessary" sub-exception requirements exceed what HIPAA requires
• Think about information blocking implications and obligations for parties with which you do business; threats and opportunities

• Physicians, other clinicians, and provider organizations will continue to view themselves as stewards of patient information and have concerns about vetting apps and API access, despite OIG guidance on HIPAA right of access
• Some organizations may face high volume of requests for information and will have challenges in handling volume
• Ambiguity in definitions and policies will make planning for compliance harder (e.g., actors, EHI vs. PHI, etc.)
• Audits may later show what you thought was best and sufficient effort not good enough, leading to unexpected liability
Information Blocking Practices
Implementation and Compliance Implications and Needs

*Aren the ONC examples unambiguous and sufficiently specific?*

- Examples generally reasonable given underlying statutory and regulatory definitions of information blocking, recognizing areas of ambiguity
- In many ways, examples appear to be catalog of complaints to ONC from stakeholders and can be understood as high priority concerns that will/should motivate enforcement and compliance; there are, however, specific issues per the below points:
  - Recognize/clarify that definition of *Electronic Health Information* (EHI), central to these practices, is not limited to information used for treatment
  - “Promptness” (e.g., for security vetting) is subjective and subject to fact situations
    - General concern if term in a practice example, like “promptness”, does not have a corresponding reference in an exception
  - Another issue relates to ONC practice example for information release, when a provider has capability to do same-day release but takes several days
    - Such a delay could be reasonable, for example if provider must deal with flawed authorization form, missing key elements in release or a bad signature
    - Technical and even process capability may not offset situational specifics
Implementation and Compliance Implications and Needs:

Do you disagree with any of ONCs identified practices?

• Need clarification on whether state or local government would be Actors (e.g., an HIE or HIN), and subject to enforcement
  – If so, several practices would be problematic for government public health agencies

• References to “optional” vs. “required” aspects of standards examples do not align well with how optionality viewed in implementation guides or world of implementers; for example, "optional" generally viewed as optional.
  – Implementation guides usually specific to use case(s)
  – What if optional extension not used exactly as described in the standard or the required part of the standard is not used exactly as prescribed
  – General point: examples and enforcement need more nuanced view of how standards are implemented

• With respect to “[h]ealth system policy requiring consent to exchange EHI for treatment even though not required by law,” workgroup members emphasized that multiple federal and state laws at play and important for OIG and ONC to coordinate with SAMSHA (42 CFR Part 2) and state agencies to reduce confusion on how to interpret and harmonize non-HIPAA privacy regulations, which could affect information blocking
  – Is failure of EHR to segregate Part 2 data, which could hinder interoperability (e.g., all data for a patient excluded from exchange), information blocking?
  – Decisions on whether to segment at record or data element level could affect ability to exchange data
Implementation and Compliance Implications and Needs:

Do you disagree with any of ONC’s identified practices?

- In addition, a vendor may build a capability that a client (e.g., provider or HIE/HIN) chooses to not acquire or implement (e.g., data segmentation)
  - Is provider decision not to acquire or use a capability information blocking, especially when there are cost and ROI considerations for deploying specific capabilities (e.g., the cost to a provider to implement data tagging and segmentation)?

- What is a vendor’s obligation to develop and offer capabilities that could enhance interoperability, especially with respect to supporting certain regulatory requirements?

- Important to recognize a provider’s conservative approach to HIPAA compliance may be well within accepted legal and compliance approaches, especially given concerns with OCR enforcement of HIPAA requirements
  - How will OCR compliance concerns be balanced with OIG/ONC compliance concerns?

- Was a sense (and a concern by some) that Cures and information blocking regulations will eliminate any “wiggle room” in implementation of HIPAA and 42 CFR Part 2 and other privacy and security regulations, some of which have conflicting imperatives (e.g., protect information vs. release information)
Implementation and Compliance Implications and Needs:

**Are there examples where “likely” standard especially problematic?**

- Concern when “likely” standard in ONC information blocking definition paired with “knowledge” standards, which are applied differently by type of actor
  - Challenging for HIE (as intermediary) to know which "likely" interpretation to follow; their own or members’, which may have different preferences and policies
- HIPAA sometimes authorizes release of information outside of Treatment, Payment or Operations, such as for research via an Institutional Review Board (IRB)
  - Can an outside organization cite its own IRB as a rationale to demand exchange?
- “Likely” already coming into play
  - Some companies are demanding immediate information release based on what responding provider views as deficient authorization forms
  - At what point does vetting equal information blocking, especially given “likely” standard?
  - From Release of Information Vendor perspective, there are times when bad actors submit authorizations for release
Implementation and Compliance Implications and Needs: *Are needed examples missing?*

- Vendors charging providers for development or implementation of data segmentation capabilities or other regulatory support
- More definition needed re: “reasonable” costs/fees
- Need examples of "without special effort" and for actor use of third-party developers that may have "all or nothing” consent policies
- Need examples that address *writing* to an EHR as “use”
  - Writing much more complex than read access, from a technical, operational and health information management (HIM) perspective
  - Latter issue goes to important role of the HIM function in validating information entered into medical record (e.g., via app or HIE)
- Is an unreadable C-CDA information blocking and what makes a C-CDA unreadable, the vendor implementation or the sending organization’s documentation practices?
- General recognition/concern that information blocking will be “weaponized” via private party negotiations, creating de facto, but private sector, enforcement
- With these and similar examples, ONC and OIG would have extreme discretion on practices to deem information blocking and select for enforcement
Recovering Costs/RAND Licensing
Implementation and Compliance Implications and Needs

Likely additional documentation burdens for cost-based pricing

- This approach to pricing would be a major departure from current practice.
- General concern: could be a burden and have a chilling effect on development, especially for developers and HIEs.
  - But likely not for providers or others do not charge for information release.
- Level of burden driven in part by extent of “interoperability elements” that are ultimately found subject to information blocking in ONC final rule and needing exception (e.g., API used for data access vs. entire EHR).
- Uncertain on accounting granularity needed: more granular = greater burden.
- Pricing and accounting under review by organizations given proposed rule.
- Required detailed cost accounting could reduce services from developers, etc.
- Uncertainty/concern whether and at what level costs would need to be disclosed to/auditable by regulators and especially data requesters.
- “Reasonableness” will depend on facts and circumstances per ONC - who needs to be convinced pricing is reasonable and what documentation needed?
Implementation and Compliance Implications and Needs

Likely additional documentation burdens for cost-based pricing

- May need detailed information on customers and their competitors to ground cost/price documentation in factors like “similarly situated,” (e.g., bed size data)
- Will be very challenging to be consistent across all “similarly situated” clients given variability of circumstances, especially for development and implementation costs
- Cost data are proprietary and unclear how this exception addresses that issue
- Anti-trust issues for cost disclosure to competitors (e.g., issue of input price disclosure – see https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/price-fixing)
- How often will pricing need to be revised as costs are recovered over time?
- How long should cost recovery take, especially as customers leave and arrive and products/services are updated – issue of dynamic vs. static cost structure?
- Need to address cost recovery for non-standard development and implementation, which will be unavoidable in many cases (and need clarity on what costs for “non-standard” implementations are defined/recoverable)
- To avoid unintended consequences, ONC should consider higher-level approach focusing on non-discriminatory, transparent and consistent pricing (allowing “apples to apples” comparisons), without need for detailed cost accounting. Cures would permit such an approach as HHS has wide discretion on exceptions (recognizing pricing concerns were major driver for underlying Cures provisions)
Implementation and Compliance Implications and Needs:

Terms likely to be most problematic (e.g. “reasonable”)

• Need very clear definition of terms, especially “reasonable” costs
• Ambiguity around key terms, and broader pricing-related exception issues, could have a chilling effect to business entry and conduct
• Higher-level focus on pricing transparency can offset need for terms needed for detailed cost accounting approach
Implementation and Compliance Implications and Needs: *Issues with cost allocation across customers*

- Cost allocation across customers will be very challenging and need to account for allocation and reflect in prices could radically alter business practices.
- Impossible for developers to know which customers will want technology under development when pricing determined as part of go-to-market plan.
- Should costs only be allocated over actual customers or over the potential, applicable customer base?
- If development for one client, but potentially applicable for others, need way to price that does not penalize this one client or lead to unsustainable pricing given market dynamics (are cross-subsides prohibited?)
- Again, a higher-level focus on non-discrimination could obviate the need for detailed cost allocation.
Implementation and Compliance Implications and Needs:

*Pricing based on customer size as preferred approach*

- Non-profit pricing partially grounded in expected costs but also reflects need to be able to invest in future projects
- Pricing based on customer/member size (e.g., revenue, employees, number of beds, etc.) common for non-profits (e.g., industry collaboratives and HIEs)
- Customer size can be reasonable proxy for level of support effort an organization will require
- Pricing by customer size can reflect concern with fairness/ability to pay
- Non-profits would need to invest in more detailed cost and market analyses to rigorously assess role of size as cost proxy and fairness issues
Implementation and Compliance Implications and Needs:

*Familiarity with RAND licensing*

- Very low familiarity with RAND licensing among workgroup members and this lack of familiarity likely widespread across community of actors.
- While often used by Standards Development Organizations which incorporate the intellectual property of third parties into the standard, it is not clear that RAND is a good fit for terms of licenses to software that developers are selling to customers in a commercial marketplace.
Implementation and Compliance Implications and Needs:

*Software typically sold via a license that could be subject to RAND*

- Much health IT software sold via a new or existing license
- Compliance will likely increase costs of doing business
- Regulators and actors will need clarity on when cost vs. RAND exception apply and whether any opportunity for strategic choice to rely on one or the other
- Unclear if intent is specific IP (e.g., a code set, patent, or proprietary API) or broader access to all IP associated with interoperability elements in any way
- Great need for clarity on scope of the interoperability elements (e.g., API or interface vs entire EHR) to which exception relevant
- Need to respond to licensing requests in 10 business days will be challenge (similar to need for timely response for “infeasible requests” exception)
- Organizations that primarily license IP could face major business model challenges, with need for non-discrimination conflicting with complex licensing scenarios
- Patent infringement subject to treble damages, reinforcing complexity of IP licensing
Implementation and Compliance Implications and Needs: How long will it take to review/revise pricing and licensing?

- For both pricing and contracting, key issue is when liability for information blocking in context of finalized exceptions begins – effective date of final rule or will there be a grace period or “learning year”?
- Time needed for review will depend on scope of interoperability elements subject to exceptions – three (3) months is best case even if very narrowly defined but more likely will be a year or more for contract and price review and revision
- If must revisit all agreements and pricing, will be very complex and time consuming – there will be an initial period and additional ongoing review for new and existing contracts and prices
- For contracting and infeasible exceptions, need processes to review “timely” or within 10 business days as applicable
- Requests for EHI/interoperability element may come from many “actors” not specified in the final rule and in unanticipated forms and channels
- More generally, need to establish and document processes for timely handling
Developing a Compliance Framework for the Information Blocking Rule
Why is Compliance Important?

• Actors face **substantial penalties** for violating the Cures Act prohibition on information blocking

• Actors have the **burden of proof** that their practices which restrict the free flow of health information fit within one of the 7 exceptions

• Software developers **must attest** to ONC that they are not engaged in information blocking and inaccurate attestations will result in sanctions

• Compliance will not “just happen” without planning and effort
OIG Compliance Program Framework - 7 elements

1. Written standards of conduct that affirm organization’s commitment to achieving and maintaining compliance
2. Designation of a corporate compliance officer and other bodies that report directly to the CEO and governing body
3. Regular and effective education and training for staff
4. Implement a complaint process that protects anonymity of the person reporting, e.g. “hotline”
5. Effective response to complaints and discipline of those who break rules
6. Monitoring the compliance program for effectiveness
7. Investigate and remediate systemic problems
Information Blocking Compliance Framework

• Why use the OIG framework?
  – The OIG model compliance plans have been around for over 10 years and healthcare industry organizations have built their compliance programs based on this guidance
  – Using the OIG elements also makes sense because the OIG is responsible for enforcing violations of the Information Blocking Rule (in collaboration with ONC)
  – The OIG framework is based on the Federal Sentencing Guidelines for Organizations which has been used widely by the US Federal Courts in a variety of cases
Key Compliance Challenges

• Who “owns” Information Blocking compliance in complex organizations where compliance functions are spread across multiple departments?
• Will smaller Actor organizations be overburdened since they lack the resources of larger organizations?
• Educating the governing body, c-suite, staff, contractors, vendors and others about Information Blocking compliance is problematic since this is still very new with little expertise
• How are Actors supposed to balance the inherent tension between protecting the privacy and security of health information and the mandate to not engage in information blocking>
Implementation Planning
Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (1)

- Are you an “actor” and if so for which units; if “Yes,” create organizational “information blocking” project
- Identify affected teams and personnel, including contractors
- Designate an overall senior executive project owner/champion
- Establish a project management process (e.g., PMO)
- Establish internal reporting processes
- Identify/designate/train internal SMEs
- Identify external resources
- Review proposed & final rule, ONC website, industry resources
Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (2)

- Identify business risks and opportunities
- Identify risk mitigators and develop a risk management model
- Evaluate applicable *exceptions* and needed actions by team
- Identify needed/desired compliance and business actions
- Identify needed changes to contracts, agreements, licenses
- Review interoperability and data access strategies
- Review and update release of information policies
- Develop policies, procedures, training, communications plan
- Integrate with compliance plan and process
Next Steps
Next Steps

• Finalize Phase 2 PowerPoint Deliverable by January 2020 and share with:
  – Workgroup, Interoperability Matters Leadership Council, Sequoia Project Board
  – HHS
  – Public Forum participants and broader stakeholder community

• Start Phase 3
  – Calls scheduled through May 2020
  – January: Discuss Final Rule and implementation topics and approaches for focus in 2020
Interoperability Matters Priorities
Interoperability Matters

- Prioritizing and addressing what will be most impactful to the end users of the information
- Leveraging the important work in government and private sector
- Public good purpose
- A scalable, repeatable process to address barriers and interoperability to be fully realized
  - Identify – Prioritize – Convene – Solve – Implement and Share Solutions
Prioritizing Issues With The Biggest Potential

**Current Work**
- Patient Matching
- Information Blocking
- TEFCA

**Future Work**
- Data Quality
- The next major challenge
Why Data Quality? Why Now?

• Infrastructure for health information exchange is maturing
• Connectivity tipping point has arrived in some communities – and coming nationally
• Momentum and will-power to improve data quality and consistency
  – Government mandates
  – Market demand
  – Patient expectations
• Workgroup
  – Reviewing website submissions since Interoperability Matters launch
  – Open call to others to nominate themselves or others
ONC Designated Recognized Coordinating Entity (RCE) Update
Status Update – Work Completed

✓ Grant awarded 8/29/19 and announced 9/3/19
✓ Kickoff meeting 9/11/19
✓ RCE web site launched 9/30/19 [https://rce.sequoiaproject.org/](https://rce.sequoiaproject.org/)
✓ Public Kickoff call 10/7/2019
✓ QTF Scoping Discussion with ONC 10/31/19
✓ Minimum Required Terms and Conditions (MRTC) review calls with ONC Oct-Nov
✓ Stakeholder engagement strategy and implementation plan approved - Nov
✓ Started targeted stakeholder feedback re: Summary of Disclosures - Nov
✓ Additional Required Terms and Conditions (ARTCs) drafted and initial review with ONC - Nov
✓ Approval to form Common Agreement Task Force – Nov
Common Agreement Workgroup

- Potential QHINs review draft language to inform initial Common Agreement
- Covers organizations that meet the requirements to engage in exchange activities under the Common Agreement
- RCE drafting application process
- Applicants must provide sufficient information to RCE and agree to MOU and NDA
- More details to follow
Status Update – Next Steps

• Work in Process
  – Prepare for targeted stakeholder feedback sessions
  – Focus group regarding Summary of Accounting of Disclosures MRTC
  – Prepare call for participation in Common Agreement Task Force

• Next Steps
  – Launch Common Agreement Workgroup
    • Develop application process for Workgroup
    • Develop MOUs and NDAs
    • Prepare work plan and materials
  – Facilitate targeted stakeholder feedback sessions 2019 and 2020
  – Review ONC comments regarding ARTCs
  – Working sessions with ONC to review revised MRTC contract language
  – Draft QHIN Technical Framework
  – RCE governance planning
Stakeholder Engagement Schedule (2019)

- 10/7 – Public kickoff call
- 11/19 – Stakeholder engagement plans approved & kicked off
- 12/5 – Sequoia Annual Meeting
- 12/11 – Public QTF Stakeholder Feedback Session
- 12/12 & 12/13 – Targeted Stakeholder Feedback Sessions
  - HIEs
  - Technology service providers, health IT developers, other HINs
  - Providers across the continuum
Stakeholder Engagement Schedule (2020)

• Q1 2020
  – January 2020
    • Targeted Stakeholder Feedback Sessions – health plans, consumers, government and public health
    • Common Agreement Public Stakeholder Feedback Session – mid-Jan (Date TBD)
    • ONC Annual Meeting (1/27-1/28)
  – February 2020
    • Public informational call
  – March 2020
    • Stakeholder sessions (in person – HIMSS 2020)

• Q2 2020
  – Continue public informational calls
  – Continue Stakeholder Feedback Sessions
Closing Discussion
Interoperability Matters

https://sequoiaproject.org/interoperability-matters/