Response to ONC & CMS Proposed Interoperability Rules

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Problems or Questions? Contact Dawn Van Dyke
dvandyke@sequoiaproject.org or 703.864.4062
Speakers

• Lindsay Austin, Troutman Sanders Strategies
• Steve Gravely, Gravely Group
• Mark Segal, Principal, Digital Health Policy Advisors
• Mariann Yeager, The Sequoia Project
The Sequoia Project’s Role

The Sequoia Project is a trusted, independent convener of private sector healthcare and governmental stakeholders.

We work to address the challenges of secure, interoperable nationwide health information exchange (HIE).
Sequoia Project Members
Current Sequoia Project Initiatives

**PULSE** is a system which provides disaster healthcare volunteers access to information to treat individuals injured or displaced by disasters.

**RSNA Image Share Validation Program** is an interoperability testing program to enable seamless sharing of medical images.

**Interoperability Matters** is a public-private cooperative to identify, prioritize, and solve the most pressing, discrete health information exchange challenges.
HHS Proposed Rule
Medicare & Medicaid Programs
Patient Protection & Affordable Care Act;
Interoperability and Patient Access for . . .
(CMS-9115-P)
CMS: Overall Goals & Approach

Proposal

- Enable *patients to access* their health information electronically *without special effort* by requiring payers to support open, standards-based APIs
- Ensure that *providers have ready access* to health information about their patients, regardless of where the patient may have previously received care
- Ensure that *payers make it easy to identify which providers are in a plan’s network*

Response

- *Wholeheartedly agree* with CMS’s goals and general approach
- Strongly applaud and support CMS’s work with the private sector, including the Da Vinci project and Health Level 7 (HL7®)
- *Suggest decoupling semantics of interoperability* from specific transport approaches
CMS: Tackling Information Blocking

Proposal

CMS proposes to publicly report the names of clinicians and hospitals who submit a “no” response to certain attestation statements related to prevention of information blocking.

Response

- The Sequoia Project does not have comments on this CMS proposal but does strongly support effective public and private-sector efforts to address potential information blocking.
- Shared with CMS approach taken and findings of the Information Blocking Workgroup of the Sequoia Project’s Interoperability Matters cooperative
CMS: Addressing Privacy Concerns & HIPAA

Real-World Experience

“We have seen firsthand how uncertainty about what is permitted or required under HIPAA has impeded organizational and individual willingness to share information and to engage with health information exchange, especially for allowed purposes other than treatment.”

~ Mariann Yeager
CEO, The Sequoia Project

Response

• Previously indicated support for OCR’s desire to evaluate potential revisions to provisions of HIPAA regulations that may impede transformation to value-based care or interfere with coordinated care without meaningfully protecting privacy or security of PHI

• Agree with need to strike an optimal balance between privacy and security and access to PHI to meet the range of legally and contractually permitted purposes for such information
CMS: Requiring APIs for Health Plans

Proposal

CMS proposes multiple initiatives to enhance patients’ access:
• Create new mechanisms for patients to access and direct use of their information
• Require that specified information be made accessible to patients by certain health plans via “open” APIs using content and vocabulary standards
• Require payers to make data available within one day of its receipt

Response

• Support open APIs and proposed incorporation by reference of ONC standards
• Recommend vocab/value sets used for quality measure reporting align with those used for clinical data
• Concerned about CMS’s proposed timing:
  (1) Plan adoption timetable is overly aggressive
  (2) Although we strongly support rapid and timely patient access to their data, the “one day” requirement may prove impractical
CMS: Health Plans to Use Existing Exchange Networks

Proposal

• Require that certain health plans must participate in a trusted health information exchange network meeting CMS-specified criteria by 1/1/2020.

• Request comments on payer-to-payer and payer-to-provider interoperability that leverages existing trusts networks

Response

• Strongly support focus on trusted exchange networks and networks that *that are in production now* and have proved their value in enabling standards-based interoperability

• Agree that ONC’s proposed TEFCA Draft 2 has significant promise but also agree with CMS that health plans *can add significant capabilities now*, including enhanced payer-to-payer and payer-to-provider interoperability through existing trusted exchange networks
CMS: Adding Conditions of Participation

Response

• Disagree new CoP is necessary because:
  – Other ongoing efforts (e.g., 21st Century Cures)
  – Burden on Hospitals
• Appreciate rationale for initial focus on ADT messages, but it is premature to reference a specific data transport standard

Suggestions

• Incentivize hospitals and facilities to participate in a broader set of exchange activities through networks
  – Similar to CMS’ health plan proposal
• Focus on functional need to send event notification vs specific mechanisms or standards if proposal carried forward
• Be mindful of industry comments on timing
CMS: Advancing Interoperability Across the Care Continuum

Proposal

CMS outlines issues associated with lack of adoption/use of certified health IT among post-acute care (PAC) providers and its efforts to standardize data in this area

Response

• We agree with the importance of this issue
• We note recent positive signs including:
  – A significant increase in connectivity for this community through Carequality and eHealth Exchange, even without government incentives
  – A new initiative sponsored by ONC and CMS to identify/execute on opportunities to apply FHIR to PAC interoperability
CMS: Solving Patient Identity Management Challenges

**Proposal**

CMS provides a summary discussion of the extent to which challenges in accurate patient identification and matching can be a barrier to interoperability.

**Response**

- Agree with CMS on the importance of accurate patient matching.
- Provide a review of our work and the need for private sector-led efforts with strong federal government support.
HHS Proposed Rule
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01)
ONC: Overall Approach to APIs & Standards

Thoughts on APIs

• Generally supports ONC’s approach to open APIs and the specification of several standards, including HL7® FHIR®
• Of the ONC’s options for the version of FHIR® and associated standards for the final rule, we **strongly support Option #4—FHIR® Release 4** (or the latest balloted version of FHIR®)
• Encourage and enable use of updated SDO-developed implementation specifications

Concerns About Standards & Implementation Specifications

• Suggest implementation specifications be designated in ONC guidance rather than in the final regulation
• Suggest ONC modify its conformity assessment methods to accommodate updates to implementation guidance without rule-making
• Note that, for FHIR® Release 4, the applicable implementation guide would be US Core STU 3.1.0, which is expected to be published late 2019
ONC: API Standards Suggestions

• Initial set of FHIR resources used with the proposed API, the API Resource Collection in Health (ARCH), should always be bounded by the scope of USCDI

• USCDI should only include data classes and data elements that have SDO-developed implementation guides

• ARCH should only reference HL7® FHIR® resources

• ARCH should transition as rapidly as possible to a private sector, SDO-developed implementation specification (e.g. HL7® US Core)
ONC: Challenging Proposed Timeline and Functionality

**Timelines**
- Heed providers and developers on practicality and reasonableness of proposed timelines
- Timing concerns for technology development and implementation, including complex new organizational policies

**Functionality**
- Set **realistic expectations** for revised data export functionality
- Consider feedback from developer community on the **potential challenges and cost associated** with this proposed certification criteria
CMS: Information Blocking

Very Broad Definitions
- “Access”
- “Exchange”
- “Use”
- “Electronic health information”

Impact, foreseen and unforeseen, may exceed and even be inconsistent with Congress’ intent to define and limit information blocking
ONC: A Closer Look at Definitions

“Electronic Health Information”

- Very broad definition
- Impractical information blocking application to extensive, highly situational, and largely non-standardized data set

Suggest information blocking enforcement focus on access to the evolving USDI, which is the focus of API requirements

“Health Information Exchanges” and “Health Information Networks”

- Distinctions between categories are unclear and the definitions too broad
- Unintentionally may include orgs (e.g., providers org, SDOs, etc.) for HIE/HIN fines
- Unintentionally may include orgs for very stringent requirements (e.g., on pricing and licensing) associated with exceptions relevant to these actors
- Narrow HIN definition on operational networks and combine into one category
ONC: 7 Reasonable & Necessary Exceptions

Inadvertent Consequences

Concern with the proposed requirement that “[t]o qualify for any of these exceptions, an individual or entity would, for each relevant practice and at all relevant times, must satisfy all applicable conditions of the exception”.

• May **inadvertently ensnare many individuals and organizations** who are acting in good faith as it seeks to identify or deter a relatively few “bad actors”

• **Unintended costs** that will be result from organizations needing to manage these complex policies and to document their actions.

See published comments for additional concerns and details
ONC: Solving Patient Matching

Much of patient matching has been focused intra-organizational but true interoperability & data liquidity will require cross-organizational matching

- A case study improving inter-organizational patient matching to a greater than 95% success rate
- A patient matching maturity model to assess current state and provide a roadmap towards methodically improving
- A list of minimally acceptable patient matching practices for CIOs, CTOs and other technology leaders to adopt
Congressional Activity Around Cures Implementation

Lindsay Austin, Troutman Sanders Strategies
Next Steps

• Interoperability Matters Cooperative will continue its work, uncovering practical implications of the proposal rules and TEF.
• Information Blocking Workgroup will continue, with focus on
  – Assessments of proposed rule implications to the community; and
  – Discussions to clarify information blocking policies and considerations, including follow-up actions needed from the federal government and private sector, prior to and after the Final Rule.
Discussion
Type your question or “raise” your digital hand to be unmuted

*Your line can only be unmuted if you entered an audio pin on your phone or use computer audio
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<td>• Priority for leadership in workgroups and pilots</td>
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2019 Annual Meeting
DECEMBER 5
Thank You!

Convene  Collaborate  Interoperate