Town Hall

AIRA's DRAFT Comments on Proposed Rules from ONC and CMS
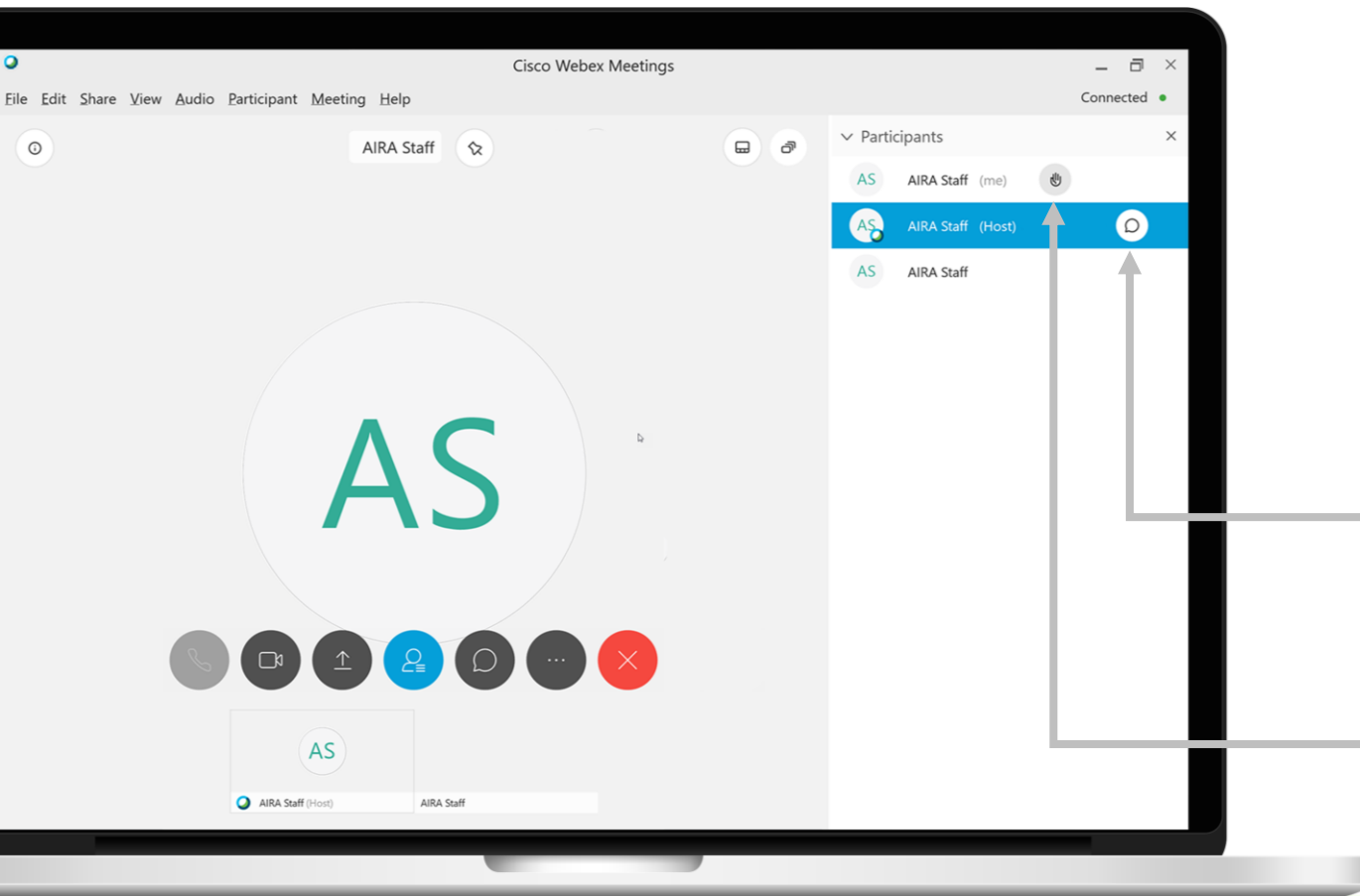
April 8, 2019

Welcome
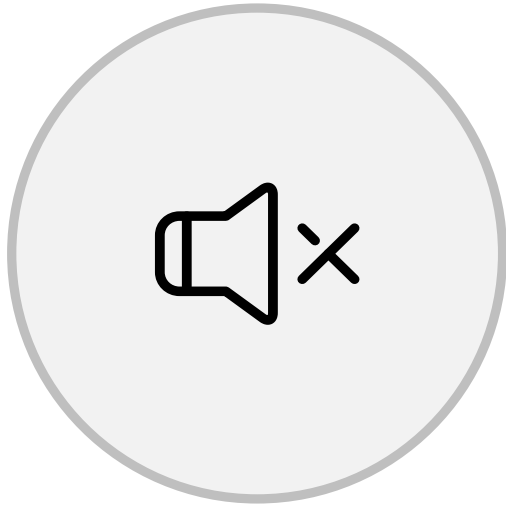
All phone lines
are muted

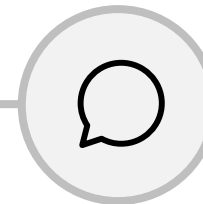This meeting is being recorded
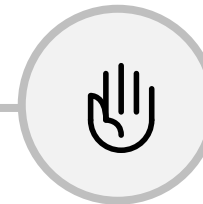and will be posted on the
AIRA repository

Welcome

How do I ask a question?

- There will be time allotted for Q&A at any time during the presentation, to unmute your line press *6

- Via WebEx:

Select the chat icon next to the host and type question into the chat box.

Select the hand icon next to your name and you will be called on.

AIRA's DRAFT Comments on the Following Proposed Rules from ONC

RIN 0955-AA01, is titled **21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program**.

- Federal Register version: https://www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

- Pre-published PDF: https://www.healthit.gov/sites/default/files/nprm/ONCCuresActNPRM.pdf

ONC Rule

- This proposed rule would implement certain provisions of the 21st Century Cures Act, including **conditions and maintenance of certification requirements** for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the **voluntary certification of health IT for use by pediatric health care providers**, and reasonable and necessary **activities that do not constitute information blocking**.

- The implementation of these provisions would **advance interoperability and support the access, exchange, and use of electronic health information**.

- The proposed rule would also **modify the 2015 Edition health IT certification criteria** and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

AIRA's DRAFT Comments on the Following Proposed Rules from CMS

CMS-9115-P, is titled **Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicare Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers**.

Federal Register version: https://www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

The pre-published PDF: https://www.cms.gov/Center/Special-Topic/Interoperability/CMS-9115-P.pdf

CMS Rule

- This proposed rule is intended to **move the health care ecosystem in the direction of interoperability**, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to **improve access to, and the quality of, information that Americans need to make informed health care decisions**, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers.

Process Considerations - Timeline

- **March 29, 2019**: Comments were due from AIRA Community
- **April 8, 2019, 3pm ET**: Town Hall to review comments and discuss rule: (register [here](#))
- **April 10, 2019**: Draft comments shared with AIRA Community
- **April 17, 2019**: Edits on draft comments returned to AIRA
- **April 22, 2019**: Final comments shared with AIRA Community to leverage in submitting their own jurisdictional comments
- **May 3, 2019**: All comments due to CMS and ONC no later than **5pm ET**

Process Considerations – ONC Template

- ONC released an optional template to use for comments – it is long (70 pages) and more structured than our usual comments (found at: https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health):

  "While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages."

- At this point, we believe AIRA concerns are better represented in our typical comment forum – a letter followed by detailed comments organized by page number and section

Process Considerations – New Acronyms

- APIs – Application Programming Interfaces
- ACBs – Authorized Certification Bodies
- CHPL – Certified Health IT Product List
- FHIR – Fast Healthcare Interoperability Resources
- EHI – Electronic Health Information
- NTTAA – National Technology and Transfer Advancement Act
- PoPC – Principles of Proper Conduct
- TEFCA – Trusted Exchange Framework and Common Agreement
- USCDI – United States Core Data for Interoperability
- 2015 CEHRT – 2015 Certified Electronic Health Record Technology

Drivers for these New Rules – Cost, Patient Safety and Access

- Estimated Costs:
  - Total annual cost for first year: $365m-$919m
  - Total perpetual annual cost (starting in year 2): $228m-$452m
- Estimated Benefits:
  - Total annual benefit for first year: $2.7b-$8.2b
  - Total perpetual annual benefit (starting in year 2): $2.9b-$8.7b

- Patient safety, access to their health information
  - *"Patient care could improve through the reduced risk of error that comes with the health care system's consistent implementation and use of health IT certified to the 2015 Edition"*

Topic Considerations

- Information Blocking
- USCDI
- Standards Advancement Process
- Real World Testing
- Voluntary HIT for Pediatric Care Settings
- Exceptions to NTTAA
- Registry and Patient Matching RFIs
- FHIR API
- TEFCA

AIRA Consolidated DRAFT Comments

Comments were drawn from a variety of sources:

- AIRA Members and Partners
- Task Force for Promoting Interoperability
- Association for PH Labs (APHL)

Note: AIRA's DRAFT comments are still a work in progress (and in some cases, may raise more questions than they answer)

Information Blocking - Context

OVERVIEW

⭐ Section 4004 of the Cures Act authorizes the Secretary of Health and Human Services to identify reasonable and necessary activities that do not constitute information blocking.

⭐ In consultation with stakeholders, we have identified seven categories of practices that would be reasonable and necessary, provided certain conditions are met.

"Actors" regulated by the information blocking provision:

- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Exchanges
- Health Information Networks

⭐ The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.

⭐ If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

Information Blocking – 7 Exceptions

- Preventing Harm
- Promoting the Privacy of EHI
- Promoting the Security of EHI
- Recovering Costs Reasonably Incurred
- Responding to Requests that are Infeasible
- Licensing of Interoperability Elements
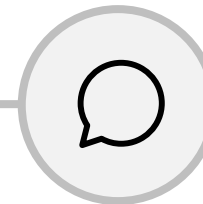- Maintaining and Improving Health IT Performance

Review of DRAFT Comments
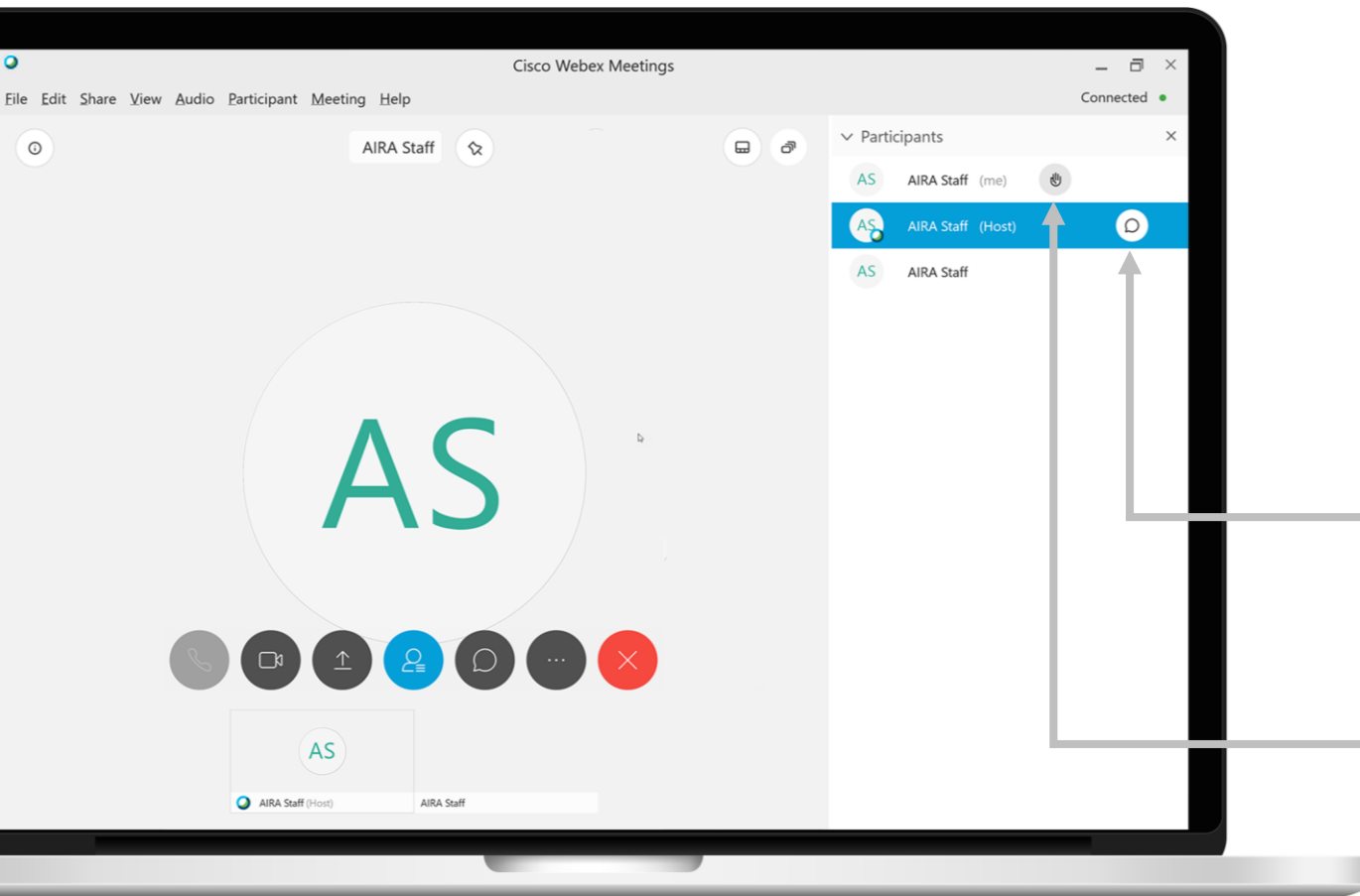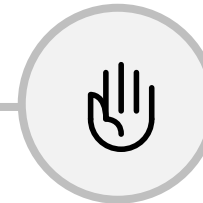
Questions, Comments, Discussion?

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Thank you for joining us!

Watch for the updated consolidated comments in your inbox