

Electronic Health Record Association Briefing on Information Blocking

June 23, 2020

Panelists:

- Leigh Burchell, Allscripts
- Hans Buitendijk, Cerner
- David Bucciferro, Foothold Technology
- Anu Nakkana, JD, Greenway

Congressional Intent

Leigh Burchell, VP of Health Policy and Industry Affairs at Allscripts, opened the briefing by explaining that information blocking and other concepts finalized in the ONC rule are going to change healthcare on a scale similar to other regulations like HIPAA or Meaningful Use. The rules require detailed attention, even as we collectively face the challenge of COVID-19, given the November 2nd deadline included in the ONC regulation.

She stressed that the EHR Association supports the intent and goals of the rule, and noted that EHR developers who adopt the Association's Code of Conduct already pledge they will not engage in data blocking.

The EHR Association appreciated Congress' open-door approach in drafting the 21st Century Cures Act, soliciting input from a range of stakeholders. Legislative interest in technology in healthcare has evolved quickly, beginning with Congress' first major health IT-related legislation, the HITECH Act of 2009, which introduced the Meaningful Use and certification programs. By 2016, reacting to concerns that information wasn't flowing between healthcare providers or to patients despite the HITECH investment in EHR-related incentives, Congress had passed the Cures Act, which focused on enhancing patient access to their data.

Despite this focus, the Information Blocking rule did not focus on the participants of the Medicare penalty program, as Congress intended. Instead, ONC issued an expansive regulation of all health IT, greatly increasing regulation of private entities beyond the government programs of certification and Meaningful Use (now called Promoting Interoperability). The rule defines electronic health information, or EHI, as any electronic information in HIPAA's designated record set, regardless of whether the records are associated with a covered entity. And the regulation stretches beyond certified products to encompass non-certified health IT, business practices, and fees charged for health IT products and services.

The HHS Office of Inspector General was tasked by Congress with serving as the enforcement authority for 21st Century Cures-driven information blocking regulations, and recently issued a proposed rule to explain how it intends to begin enforcement. Unfortunately, the proposed rule is fairly vague, making it difficult for the healthcare industry – particularly developers and healthcare providers – to adequately prepare.

Ups and Downs of the Final Rule

Hans Buitendijk, Director of Interoperability Strategy at Cerner Corporation, reemphasized that EHRA is supportive of efforts to maximize information flow between stakeholders, noting that the flow of data

needs to happen with the least amount of friction across all stakeholders. This increased focus on interoperability is essential to enable data to follow the patient and enable access across all authorized stakeholders, including the consumer. Alignment on standards for APIs was critical and supports the adoption of the HL7 FHIR standard, as well as raising the bar for document content.

EHRA particularly appreciates the increased clarity in key areas around Licensing Exception and introduction of Content and Manner Exception, as well as an initial focus on USCDI. An increased focus on interoperability and real world testing, as well as alignment of standards for API-based access are also positive steps.

“We support the progress that has been made but feel more support and guidance is needed,” said Buitendijk. Still needed are support such as a well-defined roadmap for expanding data standards beyond USCDI, in order to move toward exchanging standardly-defined EHI data in bulk. Without standard definitions, EHI will be amorphous, inconsistent, hard to parse, and difficult to use, and thus friction will be inevitable.

Additionally, EHRA requests more clarity around the information blocking exceptions and enforcement/enforcement discretion elements of the final rules and OIG’s proposed rule. The OIG enforcement process has not yet been clearly defined, and there is currently a lot of complexity surrounding exceptions around Fees, Content and Manner, and Licensing, as well as the support processes and documentation requirements surrounding requests for information and rationale for claiming the exception.

We also note that there is insufficient clarity when non-standard interoperability is not considered information blocking. While the exceptions recognize alternate methods where no standards are available or suitable yet, it is not clear whether providers that deviate from standard implementations would be considered non-standard and thus subject to information blocking claims. .

Real World Implications

David Bucciferro, Special Advisor at Foothold Technology, began by reminding listeners that EHRs are not one-size-fits-all. Although EHRA members work together to understand and implement standards, the health industry at large requires a variety of configurations to support different types of providers, settings, and patients. Different organizations and specialties have different needs, different priorities, and may not always follow the best practices recommended by their EHR developer.

While the bar has been raised around health information exchange, standards depend on all parties following them, not just EHR developers. “EHRs are the face of the issue, but we’re not the reason that best practices, standards, and priorities aren’t always followed.”

EHR developers appreciate the exceptions outlined in ONC’s final rule, said Bucciferro, but these rules must be clear. As an example, he pointed to the Content & Manner exception, which notes that if it’s not technically feasible to provide data in the manner requested, another manner may be offered. But what if the requestor declines to accept the data in the manner offered, asked Bucciferro.

He explained that we’ve already seen, with COVID-19 data requests from local, state and federal public health agencies, that agencies want similar data but in different formats. There’s a huge administrative burden in these varieties of requests, and documenting the response to each inquiry that requires an Information Blocking Exception will mean more than the “marking of some little form.” This will be impactful in different ways for big companies and small, but impactful for all.

Scope Exceptions and Enforcement

Anu Nakkana, JD, Corporate Counsel at Greenway Health, explained the analysis of potential information blocking as a series of questions:

- What data is being interfered with?
- Is the practice interfering with EHI?
- Should the actor have known?

Compliance requires clarity and predictability. Regulations must be clear and unambiguous in order for companies to build processes and train employees. Unfortunately, the rule as written remains full of ambiguities.

There has been generous interpretation of the statute, including that ONC interpreted the definition of information blocking to mean that fees charged for health IT are likely to interfere with the access, exchange, or use of EHI, and thus that they have been granted regulatory authority over prices. The Fees exception was created in the final rule, outlining permissible basis for fees & impermissible basis for fees, but this suggests extensive governmental regulation on private fees. The rule does not reflect how technology developers invest in research and development, decide where to invest innovation funds, and model prices to cover overhead costs.

EHRA has submitted more than 50 questions to ONC, and we believe that enforcement should not begin until we have answers to these questions. We also have questions surrounding enforcement, particularly the timeline. ONC has authority over 45 CFR 170, and OIG over 45 CFR 171, each with different enforcement timelines. "There is significant need for guidance from ONC and OIG."

With regards to OIG enforcement, EHRA suggests that, without additional guidance from ONC, the industry will need more time (into 2021) before enforcement begins. We also recommend:

- Advisory opinions so the industry can learn and adjust
- Relaxed enforcement for 12-24 months to allow adequate time to receive guidance from ONC and/or OIG, with scaled-back penalties during that time
- Encouragement of transparency by taking into account self-initiated corrective action plans when considering enforcement actions such as civil monetary penalties
- FAQs and published guidance from OIG as it begins to wrap its head around its new role in information blocking enforcement

Questions and Answers

Congressional Intent

1. **Question to Leigh:** *You spoke about the progression of the Cures regulation over time and the impact it could have on EHR developers going forward. Overall, how could that regulation impact the industry's ability to innovate? How does Cures fit into that larger regulatory picture?*

Answer: There is a slide in the appendix that illustrates this nicely. The pace of change and particularly regulatory attention on our industry has been rapid, probably one of the fastest changes in healthcare in modern history. Much of our business is now regulated: certification from ONC sets forth what we need to develop, and programs from CMS and other government or state agencies dictate what our clients need to do (and thus what we need to support in our products). We are committed to serving our clients and continuing to attain our certification, but we must also continue to support additional features our clients need to deliver better care -- for example, with

innovations related to new or evolving technologies like Precision Medicine and Social Determinants of Health, adjustments to workflows, and other new functionality that they want from our products. Development work needed during this COVID-19 crisis has also impacted many member companies' development roadmaps. We certainly are all committed to innovation and hope there is still room under the Information Blocking structure for us to continue to invest in innovation and respond to our clients.

Ups and Downs of the Final Rule

1. **Question to Hans:** *A healthcare delivery organization can claim the infeasibility exception if they don't believe that they can retract or segment away private information successfully. Since you spoke about the low maturity of current segmentation standards, do you think that the lack of standards will be a basis for the infeasibility exception? Do you think that the exception will be used with high frequency, and are there areas where you believe that clarification on the exception is needed?*

Answer: That's a good question because it demonstrates the interplay between the exceptions. Initially there are likely to be a number of claims utilizing the infeasibility exception, because of the privacy challenge where a document has mixed data: some protected and some less protected. As people and organizations get and share data, it will not be that easy to fully extract data at such a granular level. Data might only be labeled as private at a document level but not inside the document for each specific data element that is actually private. As a result, documents might not be able to be shared. There will be a number of situations where the infeasibility exception will be used to identify that specific scenario. Over time, as the standards mature and as we get a better understanding of how to more properly and efficiently tag the data as what is truly private and what's not at the more granular level, we are going to see the infeasibility exception references diminish for this use case. Time will tell at what frequency that will occur.

Information Blocking: Analysis of the ONC Final Rules and What it Will Mean in the Real World

Panelist Biographies



Cherie Holmes-Henry, Moderator

*Vice President, Government & Industry Affairs
NextGen Healthcare*

Cherie Holmes-Henry provides health transformation subject matter expertise and leadership for NextGen Healthcare thought leader involvement and membership in various health information technology (HIT)-related industry organizations and trade associations. She is a vital thought leader resource and speaks frequently representing NextGen Healthcare expertise at industry events, client user groups, and health reform education sessions.

Ms. Holmes-Henry's responsibilities include NextGen Healthcare federal and state government initiatives. She works extensively with key regulatory healthcare decision makers across the country. Ms. Holmes-Henry engages with state and regional Health Information Exchanges (HIEs), state primary care associations, and medical associations. She helped launch the NextGen Healthcare Payer Relations Initiative. She serves on the executive committee of the Electronic Health Records Association and serves as the current Chair of the Association. She sits on the Leadership Council and the Policy Steering Committee for the eHealth Initiative, and is an active member of both the Health Information Management Systems Society (HIMSS) and the Texas eHealth Alliance.

Ms. Holmes-Henry has been with NextGen Healthcare since 2009 and previously held several executive level positions throughout her 30-year career in healthcare, managed care and healthcare IT.



Leigh Burchell

*VP, Health Policy & Industry Affairs
Allscripts*

Leigh Burchell leads the Policy & Government Affairs function for Allscripts, including legislative advocacy and regulatory response. Her role includes speaking on behalf of the company's more than 70,000 ambulatory practices and 2,400 hospital clients to ensure that new legislation and Administration policies are supportive of the most efficient paths towards healthcare improvement. She is focused on the best way to maximize the volumes of data captured in health IT, including topics such as interoperability, public health surveillance, chronic care management, and patient data ownership. She joined Allscripts in 2000.

Burchell is active in many collaborative industry organizations, serving as:

- a recent Chair of the Electronic Health Record Association (EHRA), current Chair of both the Association's Public Policy Leadership Workgroup and Opioid Crisis Task Force, and an ex officio member of the Executive Committee;
- the EHRA's designated representative to the HIMSS Public Policy Committee;
- Chair Emeritus of the Policy Steering Committee and a current Member of the Leadership Council for the eHealth Initiative; and
- a Board member of the North Carolina Technology Association.

Previously Burchell served as Vice Chair of the HIMSS Government Relations Roundtable, an elected member of the HIMSS Nominating Committee, a member of the recently concluded AHRQ-funded Patient-Centered Clinical Decision Support Learning Network, and Vice-Chair of the Health Information Technology Workgroup within TechAmerica.

Before assuming her current role in the company, Burchell was the Executive Director of an Allscripts organization focused on the collection of best practices and dissemination of thought leadership materials on practical EHR adoption and sustainable health information exchange.

Prior to Allscripts, Burchell worked for a major Connecticut health plan where she managed a preventive medicine patient engagement initiative focused on increasing member engagement with chronic disease management. She also oversaw promotion of the country's first alternative medicine program to be launched by an insurer.

Burchell graduated from Wesleyan University in Middletown, Connecticut, with a Bachelor of Arts in Constitutional History.



Hans Buitendijk, M.Sc., FHL7
Director, Interoperability Strategy
Cerner Corporation

For more than 35 years, Hans Buitendijk has been involved in the development of health IT solutions, client consulting on strategic IT planning, healthcare application development and implementations, large scale business process re-engineering and systems integration, and complex project management, bridging the gap between business process optimization and IT support.

As Director of Interoperability Strategy at Cerner, Buitendijk primarily focuses on establishing and promoting industry standards to enable interoperability across the diverse systems prevalent in health IT. In that role he represents Cerner to a variety of organizations in various leadership roles, including the EHR Association, where he is the Vice Chair and member of the Executive Committee, Chair of the Standards & Interoperability Workgroup, and EHRA's representative on the CARIN Board. He also serves with:

- The Sequoia Project® — Carequality Board Treasurer, Carequality Steering Committee Member, Carequality FHIR Technical Workgroup Co-Chair
- HL7® — Co-Chair Orders & Observations, FHIR® Management Group Member, V2 Tooling Project Lead, V2-to-FHIR Mapping Project Lead
- Da Vinci Initiative — Vice-Chair Steering Committee
- Argonaut Project — Steering Committee Member
- FAST — Steering Committee Member



David Bucciferro
Special Advisor
Foothold Technology

David came to Foothold Technology after more than 30 years at the New York State Office of Mental Health (NYSOMH), most recently serving as the Director of the Rehabilitation Services Unit. He brings a visionary yet practical insight into program development, budgeting, performance management, and compliance culled from a distinguished career in mental health services.

David started his career at the NYSOMH in the Budget Unit and then joined the Bureau of Psychiatric Rehabilitation, where he worked with community-based providers to develop and improve a broad range of services including employment, Psycho-Social Clubs, ACT and other support and outpatient programs.

In his current role, David shares experience and technical expertise in developing compliance and program standards with providers and local governments across the country with Trainings, Technical Assistance, webinars, and numerous presentations at major conferences. Providing a special emphasis on best practices for data collection and evaluations protocols, David works with providers and organizations to improve outcomes through effective and efficient practices. In addition, he is a member of the Meaningful Use Team at Foothold assisting to ensure they meet and continue to meet MU certification standards.

David is an active member of the HIMSS Electronic Health Record Association (EHRA), a trade association focusing on collaborative efforts to improve the quality and efficiency of care through the use of Electronic Health Records (EHRs). His participation includes co-leading a sub-group of the EHRA Opioid Crisis Task Force which was convened to help foster effective and urgent solutions to combat the opioid crisis occurring in our nation. Mr. Bucciferro also serves as Vice-Chair of the EHRA Patient Safety Workgroup and is part of the EHRA Membership Committee. In addition, Mr. Bucciferro lends expertise through participation in other EHRA-sponsored workgroups including: the Privacy & Security Workgroup, Delivery System Reform Workgroup, the Public Policy Leadership Workgroup, and the Quality Measurement Workgroup.



Anushree ("Anu") Nakkana
Corporate Counsel
Greenway Health

Anushree ("Anu") Nakkana serves as Corporate Counsel at Greenway Health where she provides counsel on Health IT regulations. She is passionate about innovation in the health care industry, collaborates with cross-functional teams and provides legal counsel on a variety of product and regulatory issues.

Prior to Greenway, Anu served as corporate counsel to a non-profit hospital system based in Illinois. In private practice, she served as a legal advisor to numerous physician organizations in Florida. And in those collective roles, she not only advised executive leadership teams on transactional matters, business solutions and health care regulations but also provided counsel on fraud and abuse laws such as the Stark Law, Anti-kickback and False Claims Act.

Anu graduated from the University of Florida, magna cum laude, and University of Florida Levin College of Law. She currently serves on the Young Professionals Council for the American Health Law Association and is the future Chair of the Transactional Law Committee for the Palm Beach County Bar Association.

Information Blocking and 21st Century Cures

Analysis of the ONC Final Rules
and What it Will Mean in the Real World

Electronic Health Records Association

The EHR Association's 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to **accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care** through the use of these important technologies.



1

CONGRESSIONAL INTENT

Leigh Burchell, Allscripts

2

UPS AND DOWNS OF THE FINAL RULE

Hans Buitendijk, Cerner

3

REAL-WORLD IMPLICATIONS

David Bucciferro, Foothold Technologies

4

SCOPE, EXCEPTIONS, AND ENFORCEMENT

Anu Nakkana, Greenway Health

Congressional Intent

Leigh Burchell, Allscripts

Commitment to Interoperability

The EHR Association is supportive of industry efforts to maximize information flow between stakeholders. The commitment to data exchange and avoidance of data blocking is included in the Association's Code of Conduct.

A Timeline

2009-2011



HITECH

*Envisioned national network of **data sharing***



Certification

*EHRs are certified
CMS requires use of certified tech
Incentives and penalties*



Meaningful Use Begins

*Congress hears information-sharing
is not accelerating as expected*

A Timeline

2009-2011

2015-2016



HITECH

Envisioned national network of **data sharing**



Certification

EHRs are certified
CMS requires use of certified tech
Incentives and penalties



Meaningful Use Begins

Congress hears information-sharing
is not accelerating as expected



Congressional Hearings

HELP, E&C, Senate Finance
Theme: MU is untenable
Theme: Info-sharing roadblocks



21st Century Cures

Information-blocking defined
Penalty structure
Trusted Exchange Framework

Information Blocking

...a “practice that ... is likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information” if that practice **is known** by a developer, exchange, network, or provider as being likely to “interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information.”

42 U.S.C. §300jj-52(a)

Intent of 21st Century Cures



Goals

Address shortfalls in MU3

Revisit EHR certification

Enhance standards development

Address trust and governance



Premise

Patient should be an active participant

The data should move with the patient

Data should never be locked in an EHR



However...

Some actions that impede information flow are legitimate

ONC tasked with defining these exceptions

Information Blocking Exceptions

NOT FULFILLING

a request to access/exchange/use EHI

- ▶ Preventing Harm
- ▶ Privacy
- ▶ Security
- ▶ Infeasibility
- ▶ Health IT Performance

FULFILLING

a request to access/exchange/use EHI

- ▶ Content and Manner
- ▶ Licensing
- ▶ Fees

A Timeline

2009-2011

2015-2016

2019-2020



HITECH

Envisioned national network of **data sharing**



Certification

EHRs are certified
CMS requires use of certified tech
Incentives and penalties



Meaningful Use Begins

Congress hears information-sharing
is not accelerating as expected



Congressional Hearings

HELP, E&C, Senate Finance
Theme: MU is untenable
Theme: Info-sharing roadblocks



21st Century Cures

Information-blocking defined
Penalty structure
Trusted Exchange Framework



Info-Blocking NPRM

Too late to address MU
No focus on penalty program participants
Greatly expanded scope



EHI

Expansive definition
Defined as HIPAA's designated record set
Applies beyond covered entities



Regulatory Scope

Certified **and** non-certified products
Business practices
Fees charged for all products & services

A Timeline

2009-2011

2015-2016

2019-2020

TODAY



OIG NPRM

*Developers, exchanges, networks
Vague and ambiguous*



ENFORCEMENT

Ups and Downs of the Final Rule

Hans Buitendijk, Cerner

Ups and Downs of the Final Rule:

Certification and Conditions of Certification

We **support**:

- ▶ Increased focus on interoperability
- ▶ Alignment of standards for API based access
- ▶ The start of a roadmap to enable access to the Designated Record Set
- ▶ Real World Testing

But have **concerns**:

- ▶ Consent management
- ▶ USCDI definition and standards
- ▶ Scope and boundaries of EHI
- ▶ Manageability of EHI Export
- ▶ Enforcement discretion
- ▶ Real World Testing

Ups and Downs of the Final Rule:

Information Blocking Exceptions

We **appreciate**:

- ▶ Increased clarity in key areas around Licensing Exception and introduction of Content and Manner Exception
- ▶ Initial focus to USCDI expanding to EHI over time.

But have **concerns**:

- ▶ Complexity of Fees Exception, Content and Manner, and Licensing exceptions
- ▶ Complexity of supporting processes and documentation
- ▶ OIG enforcement process not clearly defined
- ▶ No clear path to implementing Health IT in non-standard ways

Real-World Implications

David Bucciferro, Foothold Technologies

What the Rule Means in the Real World

Interoperability was defined in the 21st Century Cures statute as: “All electronically accessible health information” to be accessed, exchanged and used “without special effort on the part of the user”.

Laudable, but not reflective of the complex interconnectedness of health care and health IT

Inadvertent Consequences



WITHOUT SPECIAL EFFORT

EHRs are not one-size fits all

- 1 Different configurations
- 2 IT priorities are different
- 3 “Best practices” aren’t always followed
- 4 Standards depend on everyone following them

The EHR is sometimes the face of the issue, but not the reason for it.

What the Rule Means in the Real World

▶ Complexity of the Exceptions model

- *Concept of Exceptions is appreciated and necessary*
- *ONC attempted to address every possible scenario*
- *Complexities and variance of health care is not that simple*

▶ Content & Manner Exception

- *Inherent conflict between some of the requirements*
 - *If actor can't fulfil request in manner requested because they are technically unable to, how do they ensure they are fulfilling the request in an alternative manner to meet content and manner exception (171.301(b)(2))?*
 - *What happens when the requestor and requestee don't agree?*
- *How to work through determinations of "alternate manners"*

▶ Licensing

- *Timelines are unreasonable, won't please healthcare organizations*

The Administrative Burden of Compliance Cannot be Overstated!

Documenting and tracking exceptions for every inquiry

How much info to be kept? For how long?

False claims still require a response

Justification of all pricing decisions

OIG's NPRM: Still too vague to know how to prepare!

Scope, Exceptions & Enforcement

Anu Nakkana, Greenway Health

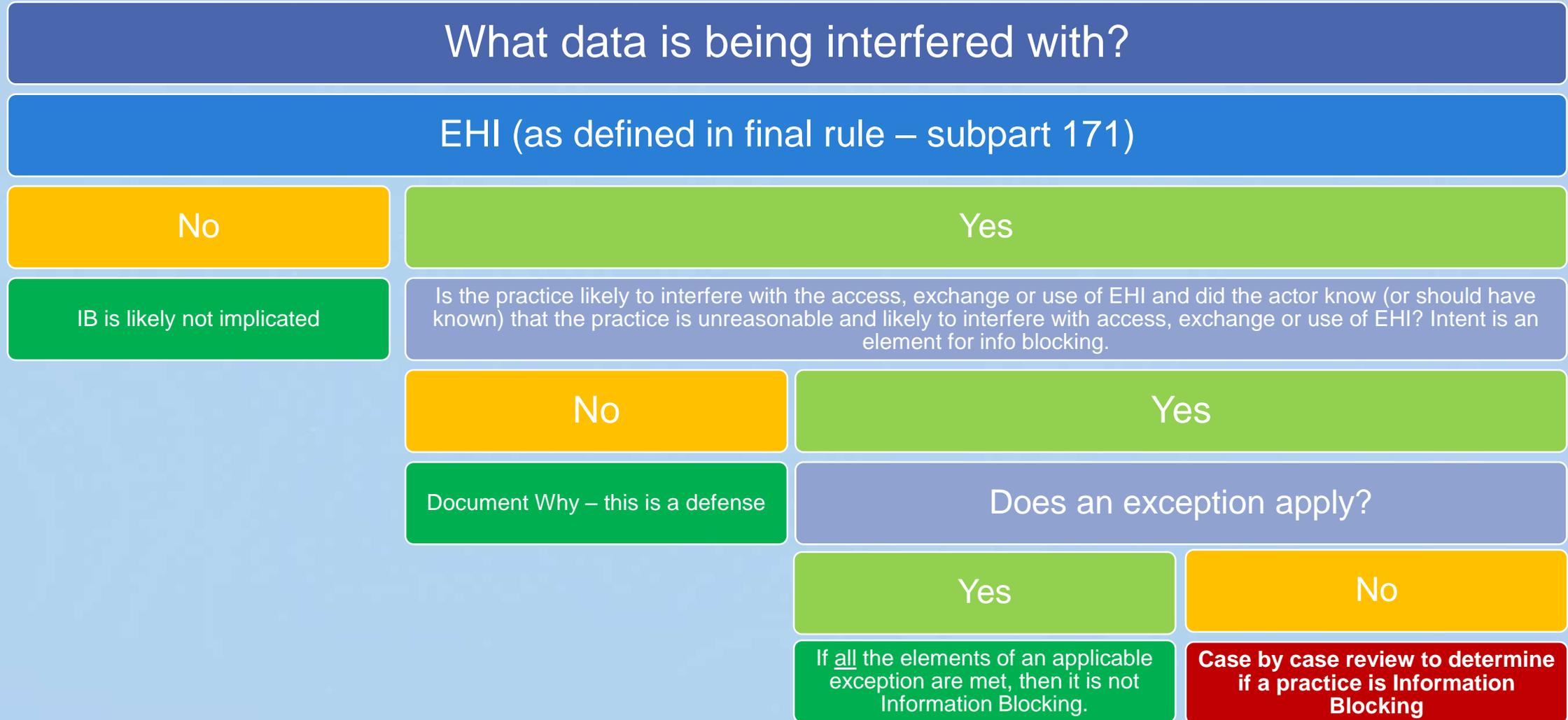
Complying with the Interoperability and Information Blocking Rule

- ▶ Compliance requires clarity and predictability
- ▶ Need clear regulations that we can build processes and train employees on
- ▶ The more ambiguous the regulation, the harder it is to comply
- ▶ Further, the broader the reach, the bigger the compliance burden

Scope of the Rule

- Broad interpretation of authority in some instances
 - Definition of EHI – Electronic Health Information – is virtually all-inclusive for companies with certified EHRs or other certified technologies
 - Has implications throughout the entirety of the rule

Information Blocking (IB) Analysis



Generous interpretation of statute



ONC interpreted the definition of information blocking to mean that fees charged for health IT are likely to interfere with the access, exchange, or use of EHI, and thus that they have been granted regulatory authority over prices



The Fees Exception was created in the final rule, outlining permissible basis for fees and impermissible basis for fees



Extensive interference re: governmental regulation on private fees



Not reflective of how technology developers invest in R&D, decide where to invest innovation funds, and model prices to cover overhead costs, among other issues



Ambiguity exists, as well

What about fees for EHI exports between Nov 2, 2020 (when enforcement begins, per ONC) and May 1, 2022 (when USCDI requirements go into effect)?

Enforcement Ambiguity – ONC vs. OIG

- ONC has authority over 45 CFR Subpart 170; however, OIG has authority over 45 CFR 171
- The misalignment presents an issue for developers
- *Civil Monetary Penalties exposure is significant, with little guidance on the mitigating factors and thresholds for penalties. Makes our job difficult.*

ONC	OIG Proposed Rule
Nov 2, 2020 with a 3-month enforcement discretion (Feb 2, 2021)	60 days after the final rule or October, 2020

Enforcement Can't Begin Until Industry Has Answers

To what extent does EHI data from “add-on” products have to be included in a CEHRT’s EHI Export functionality?

Does “all stored data” mean only active data? Could it include data entered in error and corrected?

50+
questions
Most unanswered.

Does “technical infeasibility” suffice if there are data elements of USCDI that are either not captured or not available in the manner requested?

EHI Definition is limited to USCDI for ~18 months, but compliance begins Nov 2. How do we handle requests? ONC suggests relying on Content & Manner or Infeasibility exceptions – how many Exception logs will we be noting in those 18 months?

OIG Enforcement

Enforcement flexibility suggested to OIG

With lack of guidance / answers from ONC, the industry will need more time (into 2021) before enforcement begins

Advisory opinions requested so the industry can learn and adjust

Relaxed enforcement for 12-24 months would allow adequate time to receive guidance from ONC and/or OIG

Scaled back penalties during that time

Self-initiated Corrective Action Plans should be taken into account during the investigatory process

FAQs and published guidance would be helpful as OIG begins to wrap its head around its new role in information blocking enforcement

APPENDIX

The Healthcare Industry's Expanding Regulatory To-Do List

