Interoperability and Information Blocking

What Providers Need to Know about the New Final Rules

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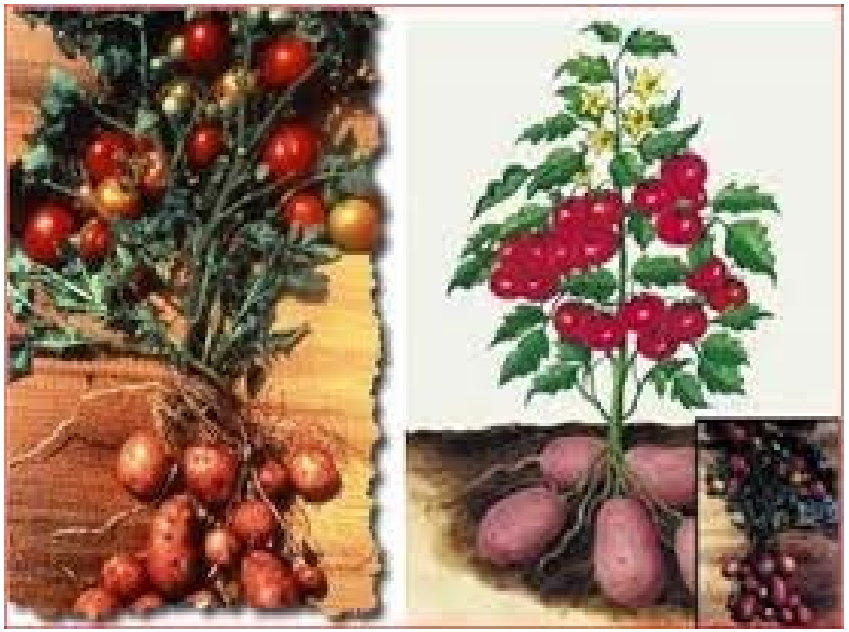
Agenda

- Overview: 21st Century Cures Act
- Information blocking
- Interoperability
- Q&A

Two Sets of Regulations: CMS and ONC
Two Plants: Tomato and Potato

- ONC: 21st Century Cures Act
- CMS: Interoperability and Patient Access



21st Century Cures Act

- Accelerate medical product development and innovation
- Prohibit information blocking
  - Any practice likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information

The Quest for Interoperability

Digital Health Broadly

Health Apps

Connected Devices / IoT

Automation and Robotics

Consumer apps and wearables

Clinical Research

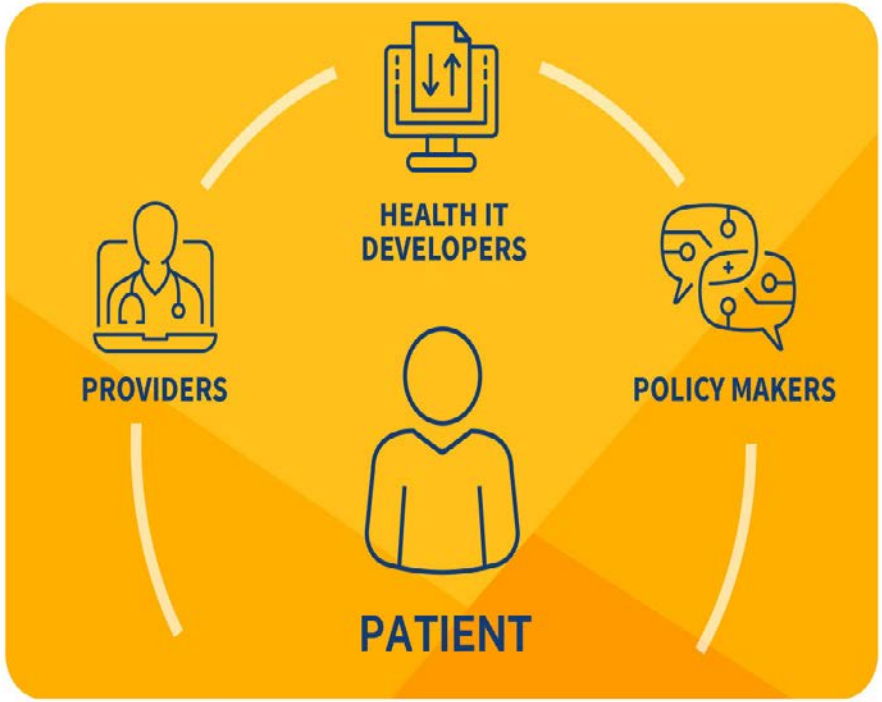
Health IT / Services

Telemedicine

Medical Algorithms

Information Blocking

- Goal of seamless and secure access, exchange, and use of electronic health information



Information Blocking

- Who is covered?
- What information is covered?
- What activities are covered?
- What are the exceptions?
- Interplay with HIPAA?

Information Blocking: Who is Covered?

- Health care providers
- Developers of Certified Health IT
  - Individual or entity that develops *or* offers Certified Health IT
- Health information networks and exchanges

Health Care Providers

- A hospital; skilled nursing facility; nursing facility; home health entity or other long term care facility; health care clinic; community mental health center; renal dialysis facility; blood center; ambulatory surgical center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.

Developers of Certified Health IT

- Individual or entity, other than a health care providers, that develops *or* offers Certified Health IT

Health Information Networks and Exchanges

- Entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information (1) among more than two unaffiliated individuals or entities and (2) that is for a treatment, payment, or health care operations purposes.

Information Blocking: What Information is Covered?

- Electronic Health Information
  - Electronic protected health information (ePHI) as defined in HIPAA, *to the extent* that ePHI would be included in a designated record set
  - Pricing information not expressly included or excluded
  - Exceptions: psychotherapy notes, information prepared in anticipation of litigation

Information Blocking: What Activities are Covered?

- Activities that make “access,” “exchange,” “use,” or “interoperability” of health data more difficult

Information Blocking: Examples

- Practices that restrict authorized access, exchange, or use under applicable state or federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies

Information Blocking: Examples

- Implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI

Information Blocking: Examples

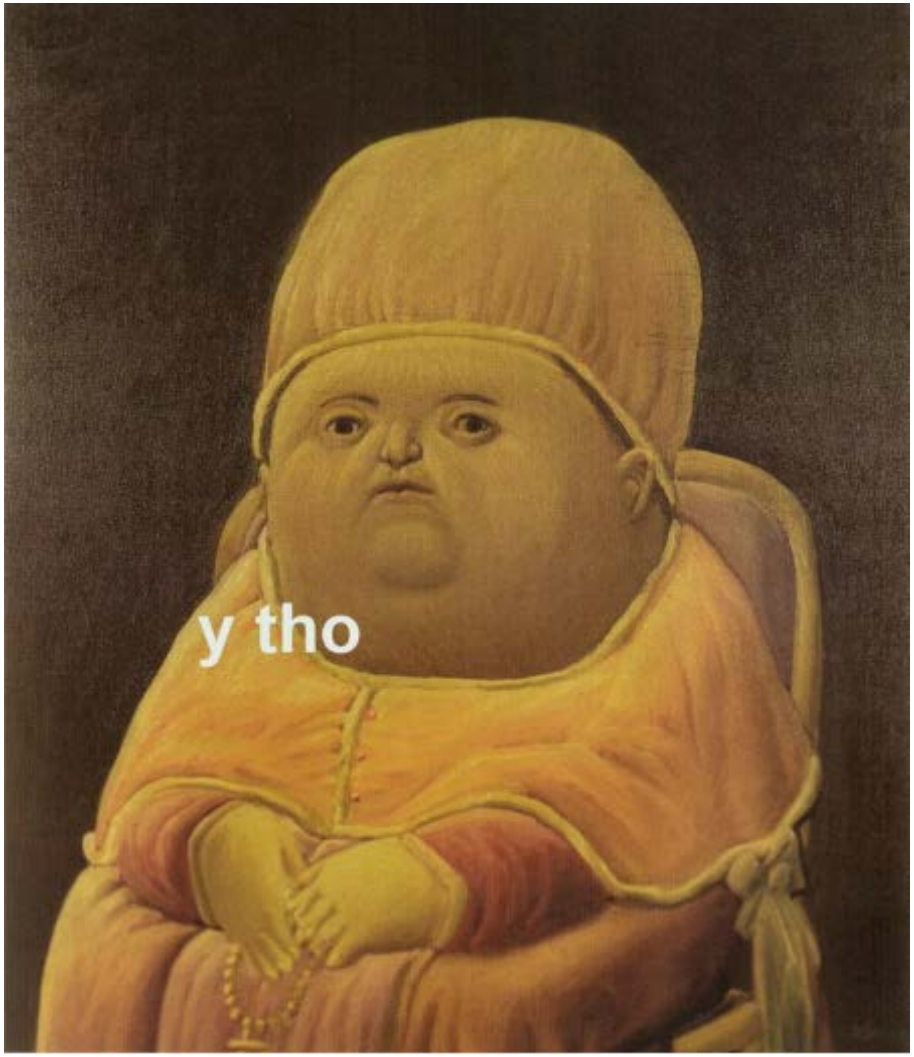
- Implementing health IT in ways that are likely to
  - Restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems; or
  - Lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT

Information Blocking Exceptions

- Exceptions that involve **not fulfilling requests** to access, exchange, or use EHI
- Exceptions that involve **procedures for fulfilling requests** to access, exchange, or use EHI

Information Blocking Exceptions

- "We appreciate that most actors will want to meet an exception to guarantee that their…practices do not meet the definition of information blocking…"
- Failure to meet an exception doesn't mean a certain practice is "information blocking"
  - But meeting an exception is guaranteed protection from CMPs or other disincentives



Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use EHI

- Preventing harm
- Privacy
- Security
- Infeasibility
- Health IT performance

Preventing Harm Exception

- A practice likely to interfere with the access, exchange, or use of EHI is not considered information blocking if reasonable and necessary to prevent harm to another person
  - Hold a reasonable belief that the practice will substantially reduce a risk of harm AND
  - No broader than necessary

THEN…

Preventing Harm Exception

- Satisfy at least one condition from each of the following:
  - Type of risk: (1) Determined on individualized basis, exercising professional judgment by health care professional with clinician-patient relationship; or (2) Arise from data that is known/reasonably suspected to be misidentified, corrupt due to technical failure, or erroneous.
  - Type of harm: one of the types of harm under HIPAA's exception to right of access for patient's life/physical health
  - Implementation basis: consistent with policy or based on facts and circumstances known/reasonably believed and based on expertise relevant to implementing the practice
- Patient has a right to request a review of an individualized determination of risk of harm

Privacy Exception

- Not info blocking to not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy
- Meet one of four criteria

Privacy Exception

1. Precondition to release not met (e.g., consent under state law)
   - Several subrequirements
2. Health IT developer of certified health IT not covered by HIPAA
3. Denial of individual's request for EHI consistent with HIPAA's right of access denial for:
   - Psychotherapy notes
   - Anticipation of trial
   - CLIA
   - Correctional institution
   - Temporarily agreed not to have access
   - In records subject to Privacy Act (federal agency records)
   - Info obtained from third party confidentially and revealing info would reveal identity of the person
4. Respecting individual's request not to share info
   - Pretty closely tracks HIPAA's requests for restrictions on use

Security Exception

- Not info blocking to protect the security of EHI
  - Directly related to safeguarding confidentiality, integrity, and availability of EHI
  - Tailored to specific security risks
  - Implemented in a consistent and non-discriminatory manner

  AND
  - Must either implement a qualifying organizational security policy or implement a qualifying security determination

Infeasibility Exception

- Not info blocking to not fulfill a request due to the infeasibility of the request if meets one of the following:
  - Uncontrollable events
    - natural/human disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike, telecom/internet interruption, act of military, civil or regulatory authority
  - Segmentation
    - cannot unambiguously segment the requested EHI
  - Infeasibility under the circumstances
    - contemporaneous written record or other documentation shows (specific) factors that led to determination; can't discriminate and make it infeasible only for some (like a competitor or someone that you can't charge)

  AND
  - Must respond within 10 business days of receipt with the reason(s) the request is infeasible

Health IT Performance Exception

- Not info blocking to maintain or improve health IT viva temporarily unavailability, or degrading performance for benefit of overall IT performance if practice is:
  - Implemented for no longer than necessary to maintain/improve
  - Implemented consistently and non-discriminatorily
  - Meet certain requirements if unavailability/degradation is initiated by health IT developer of certified health IT, HIE, or HIN
- If unavailability is response to risk of harm or security risk, only need to comply with Preventing Harm or Security Exception

Health IT Performance Exception

- An actor can take action against a third-party app that is negatively affecting the health IT's performance, if the practice is:
  - For no longer than necessary to resolve negative impacts
  - Implemented in a consistent and non-discriminatory manner
  - Consistent with existing SLAs, where applicable

Exceptions That Involve Procedures for Fulfilling Requests to Access, Exchange or Use EHI

- Content and manner
- Fees
- Licensing

Content and Manner Exception

- Not info blocking to limit the content of a response to, or the manner in which it fulfills, a request to access, exchange, or use EHI
- Content that must be provided to satisfy exception:
  - Up to 24 months after publication date in FR, must respond with, at a minimum**, the EHI identified by the data elements in the USCDI standard**
  - After 24 months from publication date, must respond with **EHI as defined** in the regs (170.102)

United States Core Data for Interoperability (USCDI) v.1

- Replaces Common Clinical Data Set (CCDS) 24 months after publication in FR
- Data class is cell header; data elements are the bullets

Changed Data Elements NPRM to USCDI v1	
Proposed USCDI	**Final Cures Rule (USCDI v1)**
Patient Demographics • Address	**Patient Demographics** • Current Address • Previous Address • Phone Number • Phone Number Type • Email Address
Provenance • Author • Author Organization • Author Time Stamp	**Provenance** • Author Organization • Author Time Stamp
Substance Reactions* (including Medication Allergies) • Substance* • Reaction*	**Allergies and Intolerances** • Substance (Medication) • Substance (Drug Class) • Reaction

*From Request for Comment on Alternative Approach to Representing Medication Allergies.

Content and Manner Exception

- Manner in which request must be fulfilled (other than as requested) to satisfy exception
  - May need to fulfill request in an alternative manner when the actor is
    - Technically unable to fulfill the request in any manner requested; or
    - Cannot reach agreeable terms with the requestor to fulfill the request
  - If request fulfilled in alternative manner, must comply with certain order of priority, must satisfy Fees Exception and Licensing Exception

Fees Exception

- Charging fees for accessing, exchanging, or using EHI won't be considered information blocking:
  - Meet the basis for fees condition (see next slide)
  - Not be specifically excluded:
    - Prohibited by HIPAA's right of access (must be reasonable, cost-based)
    - Based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual
    - To perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10) for the purposes of switching health IT or to provide patients their electronic health information
    - To export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.
  - Comply with Conditions of Certification in 170.402(a)(4) for health IT developers

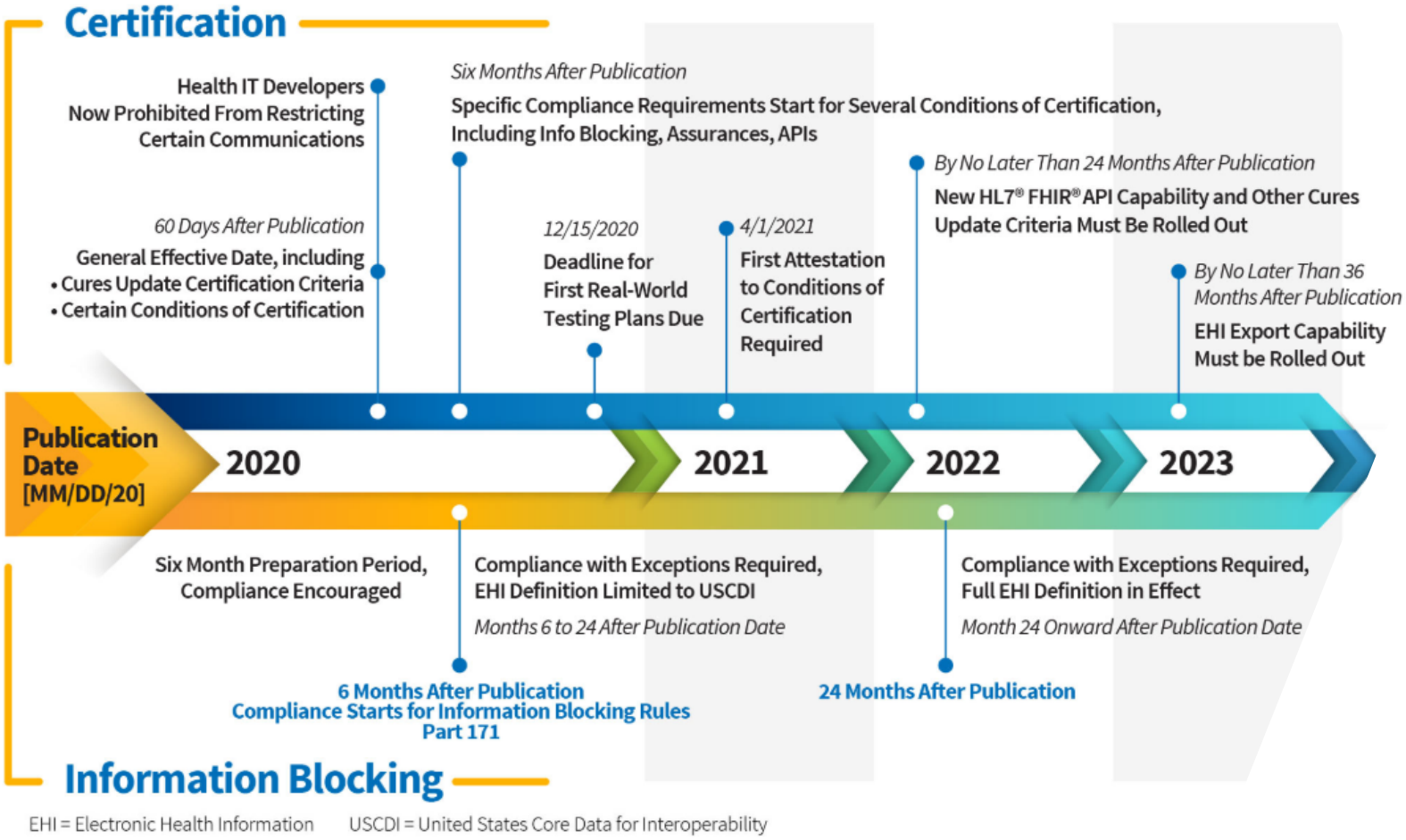
Fees Exception

- Fees must be:
  - Based on objective and verifiable criteria, uniformly applied
  - Reasonably related to the actor's costs of providing the access, exchange, or use
  - Reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported
  - Based on costs not otherwise recovered for the same instance of service to a provider and third party
- Fees must not be based on:
  - Whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor
  - Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the electronic health information
  - Costs the actor incurred due to the health IT being designed or implemented in a nonstandard way, unless the requestor agreed to the fee
  - Costs associated with intangible assets other than the actual development or acquisition costs of such assets
  - Opportunity costs unrelated to the access, exchange, or use of electronic health information
  - Any costs that led to the creation of intellectual property, if the actor charged a royalty for that intellectual property pursuant to § 171.303 and that royalty included the development costs for the creation of the intellectual property.

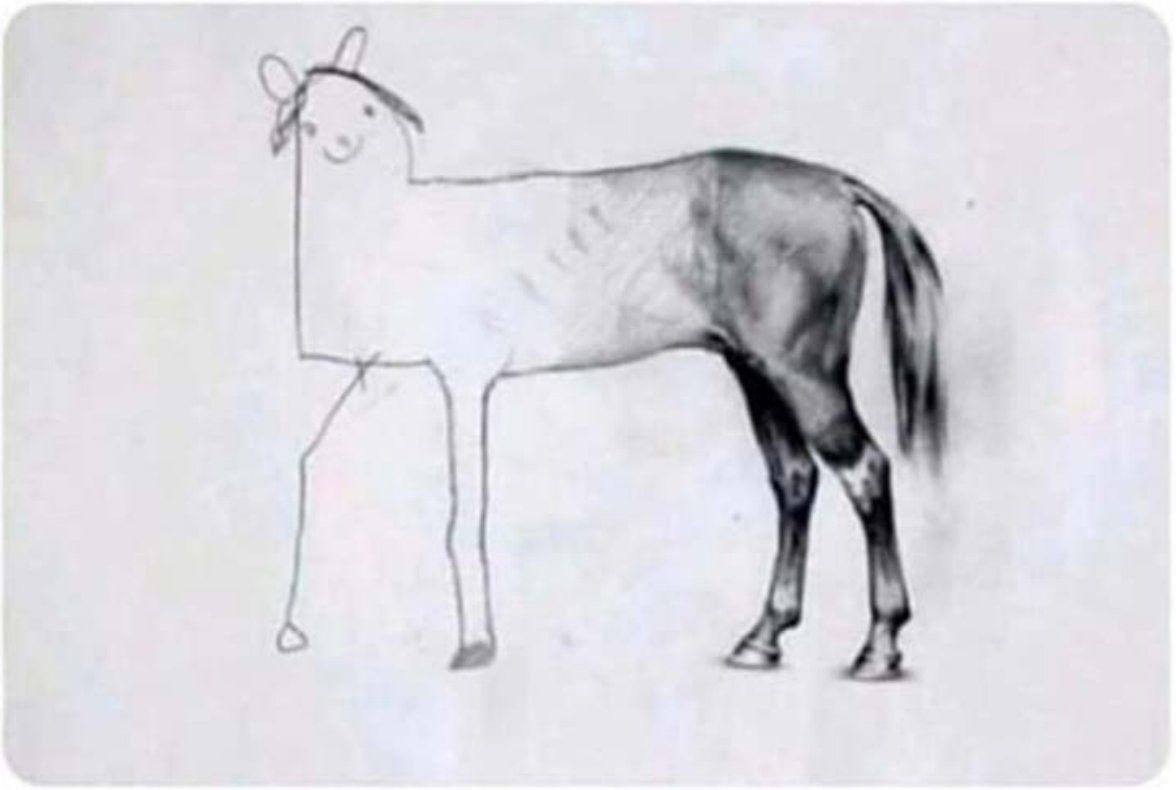
Licensing Exception

- Licensing interoperability elements in order for EHI to be accessed, exchanged, is not considered information blocking:
  - Conditions for negotiating a license for an "interoperability element": begin negotiations with a requestor within 10 business days from receipt of request and negotiate a license within 30 business days from receipt of request
  - Licensing conditions:
    - Scope of rights, reasonable royalty, non-discriminatory terms, collateral terms (no non-competes, exclusive deals, etc.), NDA ok if no broader than necessary
  - Additional conditions relating to provision of interoperability elements

ONC's Cures Act Final Rule Highlighted Regulatory Dates



When the deadline comes too close



Interoperability and Patient Access: CMS

- **Interoperability and Patient Access** for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers
  - Patient Access API
  - Provider Directory API
  - CoP on patient event notification
  - Provider digital contact info
  - Payer to Payer data exchange
  - Public Reporting and Data Blocking
  - Other miscellaneous provisions

Interoperability and Patient Access

- Goal is to give patients more rights to their information, and have health IT be able to interact better
- Applies to health care providers, but many of the provisions are for CMS-regulated payers
  - Will still affect providers, but not quite as directly
- Lots of reliance on 3rd party apps to accomplish goals
  - CMS wants the APIs to be “pro-competitive” and technically transparent, with technology that is standardized

Interoperability

- Patient Access API
- Provider Directory API
- Admission, Discharge and Transfer Event Notifications
- Payer to Payer Information Exchange
- Public Reporting and Information Blocking
- Other Miscellaneous Provisions

Patient Access API

- Payers must implement patient access open API January 1, 2021
- Allows 3rd party apps to retrieve adjudicated claims, encounters with providers, clinical data (including lab results), with dates of services after Jan. 1 2016 (!)
  - Delivered one business day after claim is adjudicated or encounter data received
- CMS doesn't regulate the apps (the FTC does)
  - Plans must educate enrollees about risks associated with sending health info to 3rd party apps
  - Payers are supposed to do a risk analysis for each app

Patient Access API

- CMS notes “Medicare Blue Button” experience since 2010
  - Medicare beneficiaries are able to download claims/encounter data through MyMedicare.gov.
  - Blue Button 2.0 modernizes, allows beneficiaries to access through APIs
  - Today has info on 53 million beneficiaries; “over 53,000 beneficiaries have taken advantage of Blue Button”
    - .1%

Provider Directory API

- By Jan. 1, 2021, plans must make standardized info about their provider networks available through a public provider directory API
- Update the information within 30 days of receiving a change
  - Enrollees still encouraged to “check with a new provider about network participation to avoid surprises” as they continue to work on improving accuracy of directories

Interoperability: Payer to Payer Information Exchange

- CMS-regulated payers are required to exchange certain patient clinical data) at the patient's request
- All payers required by January 1, 2022 to implement a process that allows electronic health data to be exchanged between payers
  - CMS does not specify the means by which payers must exchange this data
  - does not apply to state Medicaid and CHIP agencies

Interoperability: Public Reporting and Information Blocking

- CMS will publicly report eligible clinicians, hospitals, and critical access hospitals that may be information blocking based on how they attested to certain Promoting Interoperability Program requirements

Patient Event Notification

- Admission, Discharge and Transfer Event Notifications
  - Don’t have to include diagnosis
  - Can use HIE to send
  - Includes ED registration and then admission as inpatient
- New **Condition of Participation** for hospitals, psychiatric hospitals, and critical access hospitals
- Applies six months after finalization of the rule
- Applies only if the hospital’s EHR meets the content exchange standard
  - Per CMS, it is easy to obtain this information from a hospital’s health IT developer

Patient Event Notification

- Now limited set of recipients—those primarily responsible for a patient's care:
  - PCP, established primary care practice group, others identified by the patient as being responsible for patient's care
- Don't have to use a specific technology to send the notifications
- HIPAA and state law: still pay attention to patient requests to not send info to a particular provider/request restrictions
  - This seems difficult to implement given timelines for sending notifications

Provider Digital Contact Information

- CMS will start publicly reporting (late 2020?) providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System (NPPES)
- "Making the list of providers who do not provide this digital contact information public will encourage providers to make this valuable, secure contact information necessary to facilitate care coordination and data exchange easily accessible."
  - Use of "Direct address": similar to email address but with additional security measures

Provider Digital Contact Information

- Providers can review info on the NPPES NPI Registry: https://npiregistry.cms.hhs.gov/
- CMS has promised to release additional information on public reporting mechanism, including where they're going to publish names/NPIs of providers without digital contact info

What about HIPAA?

- Mostly HIPAA remains untouched by the Cures Act and Interoperability.
- Covered entities will still need to comply, but will need to consider whether a particular practice is actually prohibited by HIPAA, or is just the way it's been done for years.
- But HIPAA doesn't apply to third-party apps
  - Much more of a "buyer beware" situation
  - Reliance on patient education and disclosures (and ToS)
  - Also not appropriate to have a payer to have a BAA with the apps

Opportunities and Challenges: App Developers, Tech Companies, Investors

- Patients will be able to share records with apps
  - Such as medication managers, diagnostic services, and price comparison tools
- Patients will be able to connect records to digital devices
  - Such as glucose monitors and blood pressure cuffs
- Patients will be able to manage health via smartphones

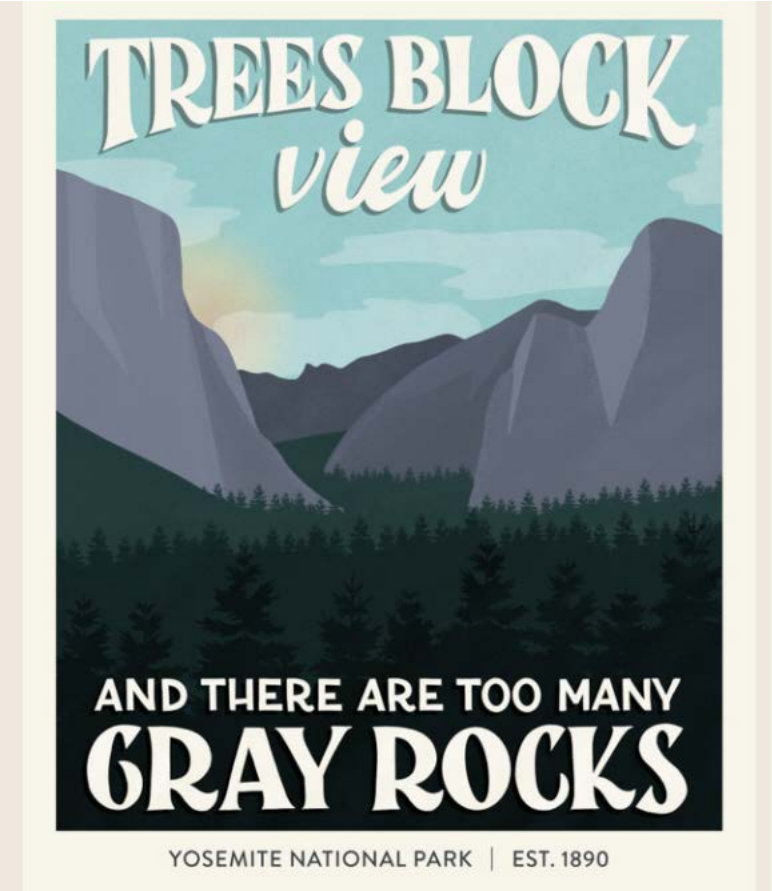
Opportunities and Challenges for Hospitals and Health Systems

- Potential to work closely with referring providers to produce better patient care results
- Compliance and IT need to work closely to implement
- Should be simpler and cheaper (eventually) to get patients access to their own info
  - "without any additional action on the part of the provider other than the initial effort to enable the technical capabilities"
- Easier to move between software providers, shouldn't be held hostage because a developer holds IT/information
- Better patient matching?
- Improved patient safety?

Q&A

Please give us your feedback!

(Actual Yelp reviews of national parks, as illustrated by Amber Share)



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