



# Cures Act, Information Blocking – It takes a Village

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## Agenda

- ▶ Cures Act 101
- ▶ Why a Multi-Disciplinary Approach
- ▶ Problems you didn't know you had
- ▶ Resources outside your Village
- ▶ April 5<sup>th</sup> has past...am I done!?

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## Cures Act 101: Information Blocking

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### What is the Cures Act?

- ▶ In 2016 the 21<sup>st</sup> Century Cures Act was passed.
  - ▶ In May 2020 the Office of the National Coordinator for Health Information Technology (ONC) published a final rule: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program in Federal Register Vol 82, No 85, beginning on page 25642 (hereinafter referred to as the "Cures Act") to implement certain provisions of the 2016 Act.
  - ▶ These regulations were scheduled to go into effect November 1, 2020, but were postponed until April 5, 2021 given the public health emergency.
- ▶ Purpose:
  - ▶ To increase a patient's ability to have access to their electronic health information and have more control over their information.
    - ▶ Promote interoperability
    - ▶ Prevent 'information blocking' practices or other anti-competitive behavior
    - ▶ Allow patients to access their electronic health information through different forms of technology (i.e. smart phone applications, application programming interfaces "APIs")

Note: All page references in this presentation are for Federal Register 2020-07419, Issued May 1, 2020  
**21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule**

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## What is it

### ★ What is information blocking?

A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.



*Note: Information blocking is prohibited under the 21<sup>st</sup> Century CURES Act*

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## What are examples of information blocking?

- Implementing health information technology 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 information technology 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 information technology
  - Imposing formal or informal restrictions on access, exchange, or use of EHI
  - Implementing capabilities in ways that limit the timeliness of access, exchange, or use of EHI
  - Discriminatory practices that frustrate or discourage efforts to enable interoperability
- ?? If a practice were to leave your organization, would you be required to assist with converting patient records to their new EHR
- ?? Does delaying release of abnormal lab results constitute information blocking
- ?? Does denying foster parent access to a child's MyChart constitute information blocking

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## Why a Multi-disciplinary approach is important

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## Why a Multi-Disciplinary Approach?

- This is not just an IT problem!
  - At first glance people hear electronic protected health information (ePHI) and their minds immediately go to "IT".
  - As you pull back the layers of the Cures Act you start to realize this goes much deeper than IT.
- Involves the entire organization.
  - Policies and Procedures
  - Risk tolerance decisions
  - Operational decisions
  - Technical decisions

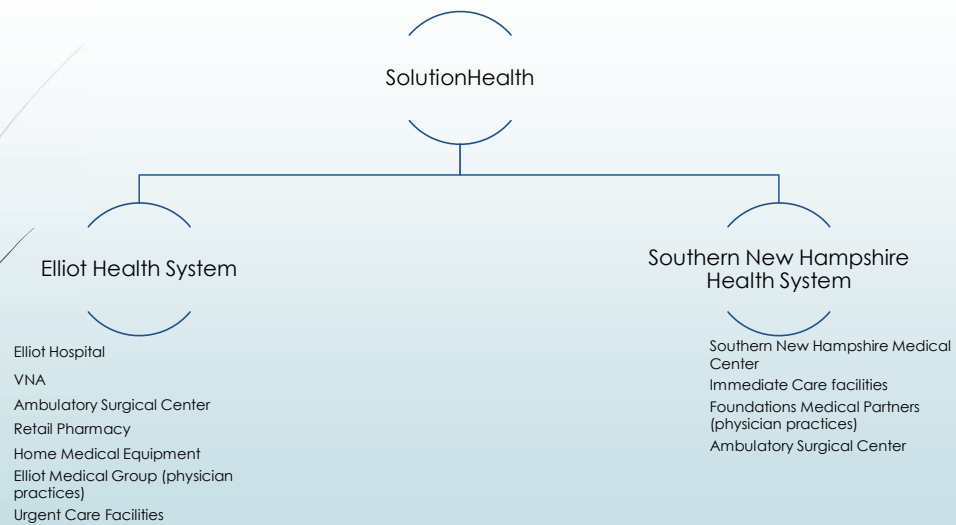
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## How do you Identify the Multi-Disciplinary Team?

- ▶ Education for managers and directors.
- ▶ Leverage current compliance/IT committees to present and start identifying key members.
- ▶ Determine a core group.
  - ▶ Do you need a Cures Act Committee?
    - ▶ Is there a need for subcommittees?
    - ▶ How do you identify other stakeholders not part of the core group?
  - ▶ Do you need project management?

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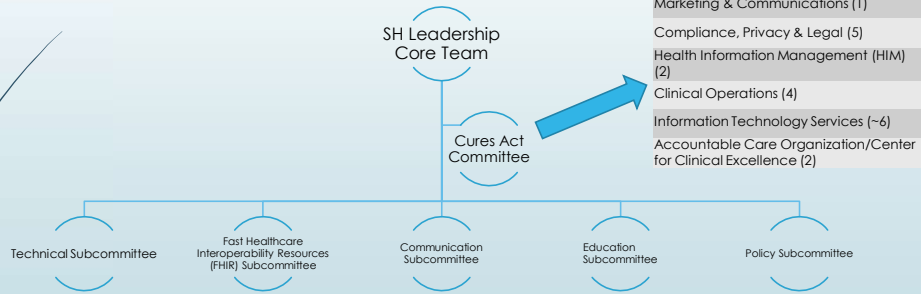
## Organizational Structure - SolutionHealth



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# Engage the Right People at SolutionHealth

## Phase 1 Approach

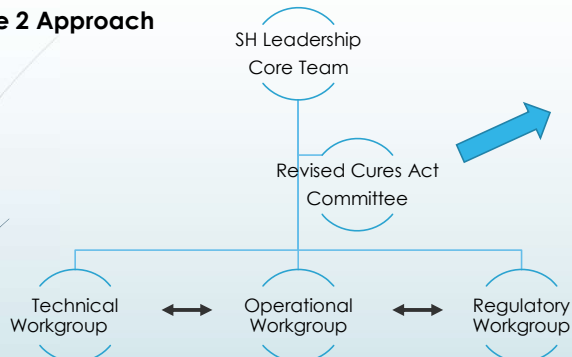


21 <sup>st</sup> Century Cures Act Committee
Chief Information Security Officer * (chair of committee)
Chief Information Medical Officer (CIMO) (2)
Analytics Resource Center (ARC) (1)
Patient Experience (1)
Marketing & Communications (1)
Compliance, Privacy & Legal (5)
Health Information Management (HIM) (2)
Clinical Operations (4)
Information Technology Services (~6)
Accountable Care Organization/Center for Clinical Excellence (2)

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# Engage the Right People at SolutionHealth

## Phase 2 Approach



21 <sup>st</sup> Century Cures Act Committee
CMIO * (1) (Co-Chair)
Compliance & Privacy * (1) (Co-Chair)
CMIO (1)
Compliance & Privacy (1)
CISO
ARC (1)
Marketing & Communications (1)
Director HIM
Clinical Applications

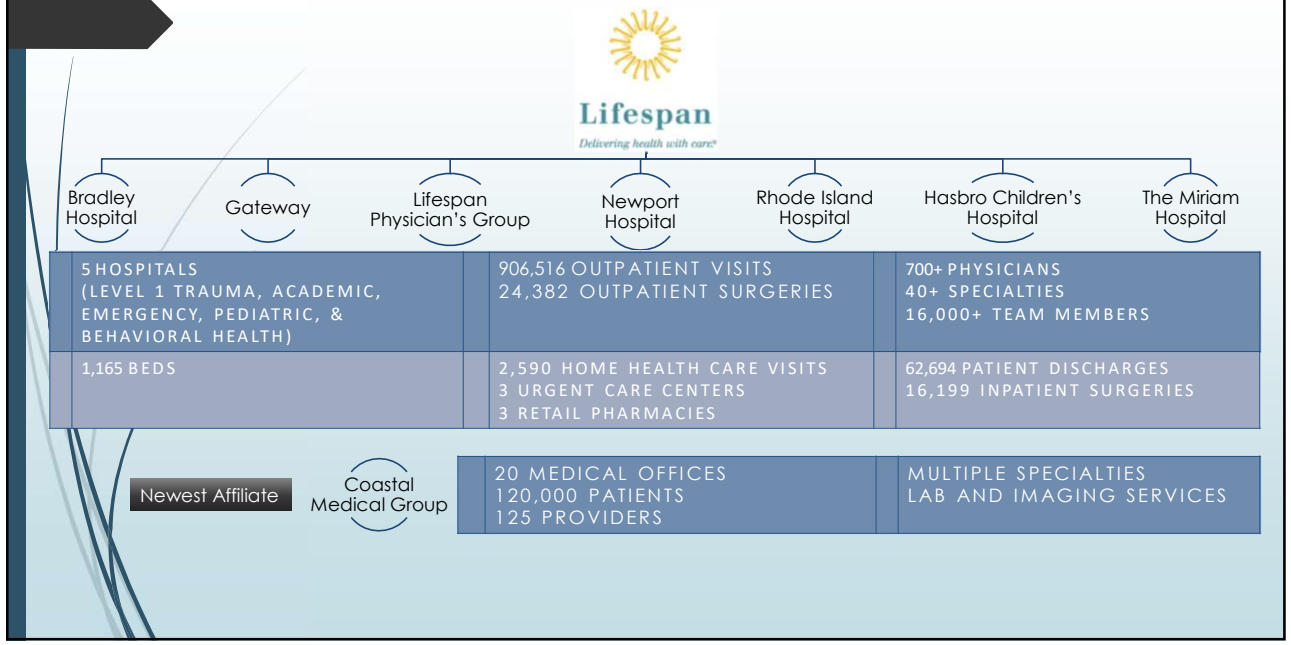
- Lead:** Clinical Applications  
**Responsibilities:**
- Discrete Data Mapping
  - Auditing
  - Apple Health
  - Epic Technical Build
  - Future versions of USCDI

- Lead:** Clinical Applications  
**Responsibilities:**
- Clinical Operations
  - Release of Information/Medical Records
  - Affiliate Relationships

- Lead:** Compliance & Privacy Officer  
**Responsibilities:**
- Monitor regulatory change
  - USCDI future releases
  - Epic Technical Build

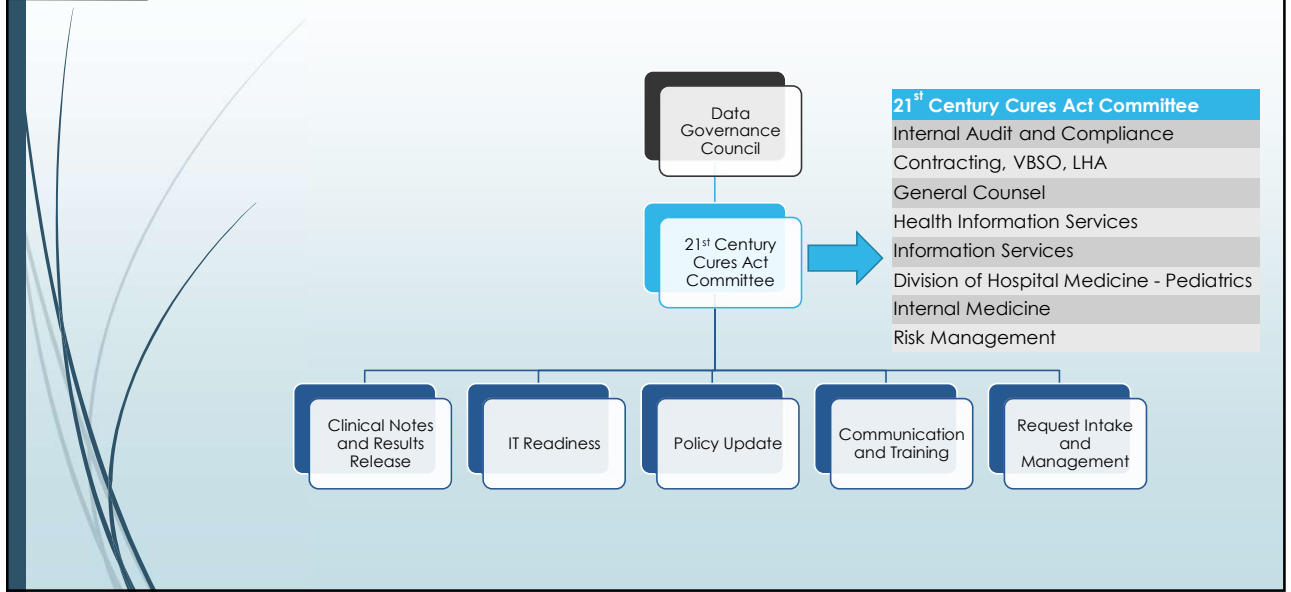
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# Organizational Structure – Lifespan



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# Engage the Right People at Lifespan



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## Problems you Didn't know you Had

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## To Share or Not to Share...That is the Question?

- ▶ To share immediately or to not share immediately?
  - ▶ Information Blocking regulations do not create a proactive requirement to immediately share ePHI with the requestor.
    - ▶ What note types should be shared immediately?; How are note types being used?
    - ▶ Sharing all license types to patient portal
    - ▶ Are you going to share lab results immediately?; If so, which ones? (pathology, genetics, HIV?)
  - ▶ Variance in State laws
    - ▶ Identifying when you are required by law to share certain health information with patients; does your system have facilities in multiple states?; do/how do state laws vary?
    - ▶ Adolescent Patient Portals
      - ▶ What healthcare services can adolescents consent to without parental consent?; How does this vary between states?; Is it driven by statutes, case law or both?

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## Thinking Strategically, Acting Tactically

### Pros: Share Immediately

- The more information that can be shared immediately, the fewer requests for information release
- Generally, patients like having information sooner
- Less likely to be accused of Information Blocking. Defending against Information Blocking is expensive.
- Generally, giving patients more information sooner is good for outcomes
- Many other organizations are sharing notes and results immediately to patient portals

### Cons: Share Immediately

- Review what can/can't be shared
- EHR technologies vary in what they can/can't accommodate
- Some disciplines have a strong culture about information sharing (Behavioral Health, Oncology, Pediatrics)

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## Culture Challenged!

- One of the biggest challenges with the Cures Act is the culture shift.
- Patients now have immediate access to health information.
  - Changes the provider/patient relationship
    - You may find disciplines that have a strong culture of doing counseling with patients when results are reviewed (behavioral health, pediatrics, oncology)
  - Concerns with documentation
    - Ex: providing tips for providers about making sure their notes contain clinically appropriate information while also incorporating
  - Concerns with the immediate access patients will have to their labs, notes, etc.
    - Ex: Reminding staff/providers patients have had access to this information pre-Cures Act.
    - Ex: Employee safety concerns with names being available via patient portal
- Education! Education! Education!
  - Email Blasts (organization, affiliates)
  - Continuing Medical Education (providers only – all credentialed providers)
    - Partner with external counsel
  - HealthStream course – organizational wide
  - Incorporate into Compliance Annual Training
  - Epic tip sheets for providers regarding electronic medical record tools to leverage applicable Safe Harbors

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## Significant Clinical Note Changes

(Auto release  
restricted  
from some  
depts.)

### Clinical Notes

(As defined in USCDI V1)

Composed of both structured and unstructured data. A clinical note may include the history, Review of Systems, physical data, assessment, diagnosis, plan of care and evaluation of plan, patient teaching and other relevant data points

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

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## Clinical Notes and Results Release

### Pedi Patient MyLifespan Accounts set up by Parents

- Discovered by a pediatric psychiatrist
- Reactivation of MyLifespan for Pedi Patients **In Process**
- We deactivated 6,500 accounts in March
- As of July 16, there are 550+ activated MyLifespan accounts for patients 12-17yo
- Modified "Adolescent" to be 13-17 yo
- New proxy class for parents of patients who are "intellectually delayed"

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Clinical Notes and Results Release

### Orders still written on hard copy forms within your system

- ▶ Intra-op orders may be written on hard copy forms by surgeons at your organization
- ▶ If you provide lab services outside your organization, those orders may be written on hard copy forms
- ▶ If you rely on the provider to mark an order result as “do not share” at the time of the order, how are you capturing that on manual orders?

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Clinical Notes and Results Release

### Reasonable people can disagree (with information sharing)

- ▶ Do individuals at your organization think all orders and results should be reviewed by them before release to patients?
- ▶ Ties in to culture shift – educating providers about having a conversation with patients when tests are ordered.
  - ▶ Do patients prefer to have labs held and released to the portal after a conversation with the provider or do patients want the results released immediately prior to provider communication?

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## You've Decided What to Share – What is Next?

- Sharing to requestors other than patients
  - Making sure traditional HIPAA release of information processes align with the Cures Act
  - Can you electronically share PHI with entities that use the same electronic medical record as you AND those entities that do not?
  - What is your process for sharing ePHI with patient's phone health care applications?
- Disseminating information about the Cures Act to staff
  - Making sure when a patient or another individual/entity makes a request for ePHI staff know how to respond.
  - Having a central repository of information.

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## Making the safe harbor a safe place

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## 8 Exceptions (aka Safe Harbor)

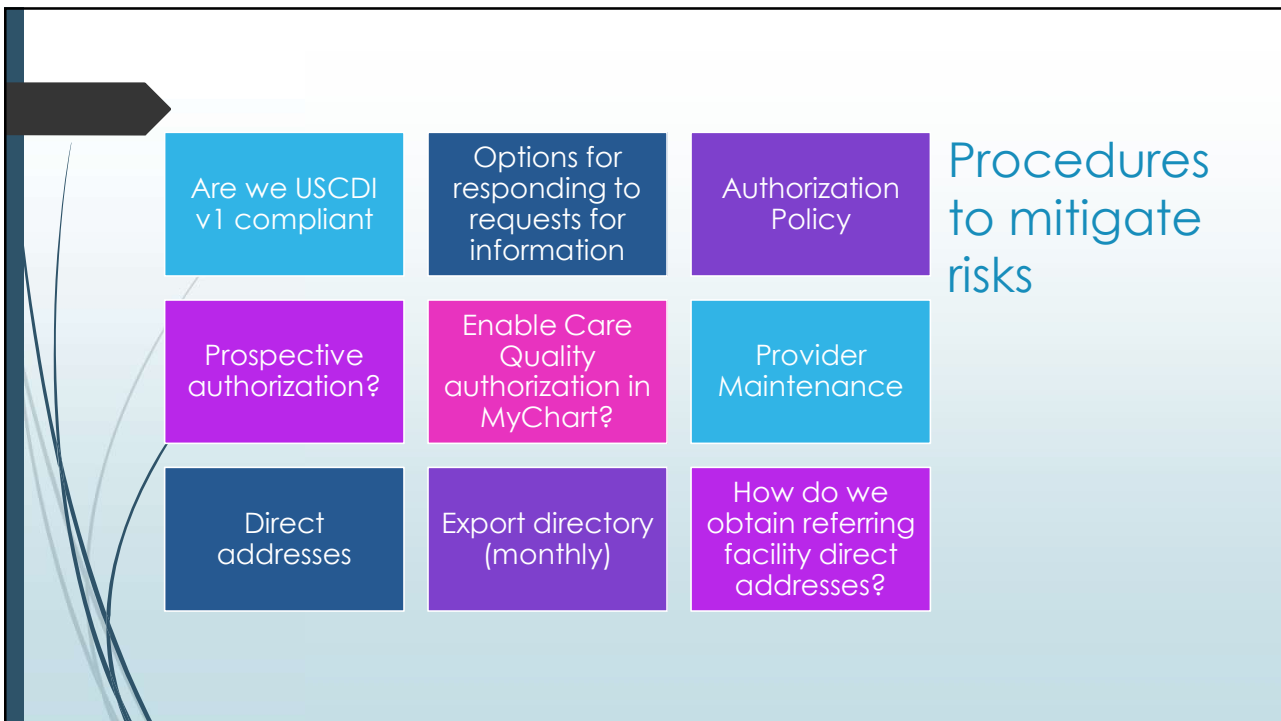
### Exceptions That Involve Not Fulfilling Requests

1. Practices that Prevent Harm
2. Privacy-Protective Practices
3. Information Security-Related Practices
4. Requests that are Infeasible
5. Practices that Maintain and Improve Health IT Performance

### Exceptions That Involve Procedures for Fulfilling Requests

1. **Content (USCDI or EHI) and Manner (agreeable terms)**
2. Recovery of Costs Reasonably Incurred
3. Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

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**Lifespan Policy on Information Blocking** New

- Time delay release of results
- Review for release denials
- Review Patient Privacy policy/information sheet
- IS Security restriction review
- Clinical Note Types

A New Universal Policy and a few of the 60+ Policies to be Reviewed

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Department Specific Communication and Training	Department	Topics
	HIM and Patient Access	<ul style="list-style-type: none"> <li>✓ Information Blocking Basics</li> <li>Workflow Changes</li> </ul>
	Privacy and Compliance	<ul style="list-style-type: none"> <li>✓ Privacy Intranet Site</li> </ul>
	Quality & Safety	<ul style="list-style-type: none"> <li>✓ Information Blocking Basics</li> <li>✓ Ambulatory Workflow Changes</li> </ul>
	MECs	<ul style="list-style-type: none"> <li>✓ 21<sup>st</sup> Century CURES and Information Blocking</li> <li>✓ Changes coming to LifeChart</li> </ul>
	Ambulatory Oversight Committee	<ul style="list-style-type: none"> <li>✓ Information Blocking Basics</li> <li>✓ What it means for Clinicians</li> </ul>

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Communication with your future self, and perhaps future others

Log of decisions that were made and why

Log of technical changes that were made and their function

Log of workflow changes that were made and the parties affected

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## EMR Functionality

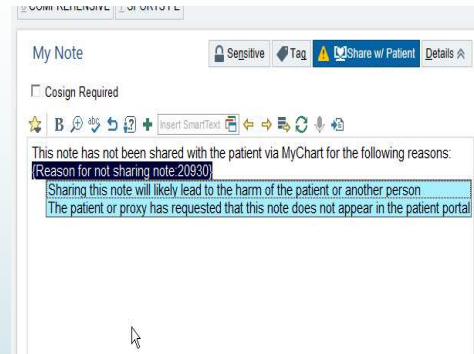
- ▶ Releasing of Results
  - For results where a provider/patient discussion is required – how will you release those? (ex: HIV results)
  - How do you not release a result based on an Safe Harbor

The image displays two screenshots of the Epic EMR interface for a 'Complete Blood Count' order. The top screenshot shows the 'Release' dropdown menu with options: 'Release', 'Hold', 'Hold until', 'Hold until 30 days', and 'Hold until 90 days'. The bottom screenshot shows the same interface with a red circle highlighting the 'Other options' link.

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## EMR Functionality

- ▶ Releasing of Notes
  - ▶ For results where the patient does not want the note shared or to fit under a Safe Harbor.



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## Resources outside your village

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## Where to go?

- What are other organizations doing in your area?
  - Use your contacts – not just Compliance, but other stakeholders as well.
  - Hospital Association – Compliance group, IT group
    - Do not be afraid to ask questions
- Electronic Medical Record (EMR) Vendor
  - Are there webinars you can listen to
  - Reach out to your vendor point person – what tools do they have in place?
  - Are there updates to your EMR that you can leverage
- Other vendors that handle your ePHI
  - Do they have user groups and/or webinars
- ONC FAQ
  - <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>
- Preamble of the Final Rule
  - <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

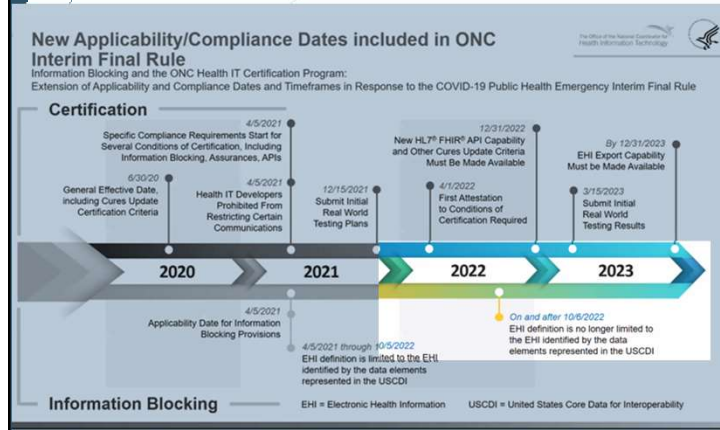
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April 5, 2021 has past – am I done?!

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# Am I Done Yet?...Not Yet!



## Things to Plan for:

1. Expansion of electronic health information definition
2. Interim changes to USCDI
3. Ongoing Governance/Cures Act Committee
4. Regulatory Changes
5. Technical changes to the electronic medical record
6. Auditing Plan
7. Ongoing Education and Communication

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# All Data

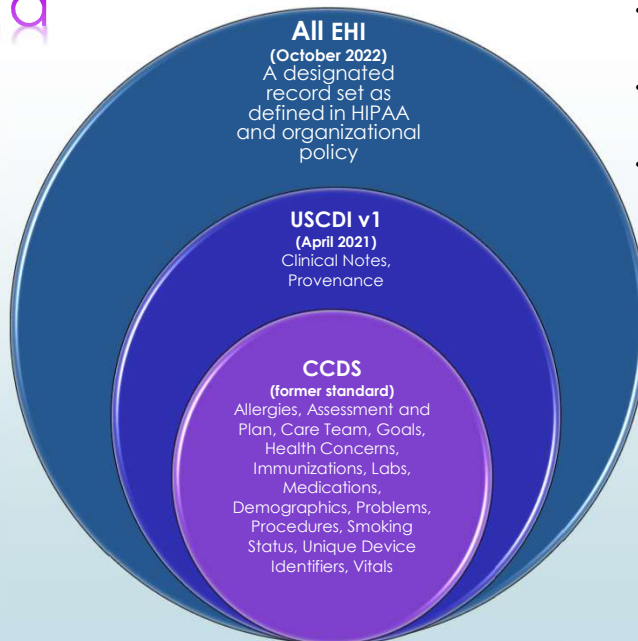
CCDS vs  
USCDI vs  
All EHI

**Common Clinical Data Set (CCDS)**

**United States Core Data for Interoperability (USCDI)**

**Electronic Health Information (EHI)**

*USCDI is a data class that can be expressed in many standard and non-standard forms*



- Has your designated record set policy been revised recently?
- What is your process for if a new services comes online?
- What is the process for when a new note type or procedure is developed in the electronic medical record?

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## Am I Done Yet?...Not Yet!

### Governance Structure & Regulatory Changes

- What structure will your organization have in place to address:
  - New services and procedures
  - Regulatory changes and impacts
  - Continuous education and training
  - Audit Plan
    - What is the report functionality of your electronic medical record?
    - Who will be conducting the auditing?

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QUESTIONS

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