



## **21st Century Cures Act: What Pediatricians Need to Know**

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# Disclaimer

- I am not a lawyer
- The information being presented does not constitute legal advice
- The information presented is my interpretation of what has been presented and discussed by leading Pediatric HIT experts as of the date of the recording
- It is the responsibility of the practice to work with their systems and advisors (medical, legal and HIT) to gain full understanding of how this will be implemented in their practice to be compliant with jurisdictional requirements

# Learning Objectives

- What the 21st Century Cures Act and “Information Blocking” means
- How this will affect your pediatric practices and your patients
- What your practice needs in order to be prepared
- What resources are available to support you



# Definitions

- **ONC:** Office of the National Coordinator
- **HHS:** Department of Health and Human Services
- **EHI:** electronically stored personal health information
- **USCDI:** United States Core Data for Interoperability
- **CDA:** a document markup standard for the structure and semantics of exchanged “clinical documents.” CDA documents are encoded in Extensible Markup Language (XML) and have “human readable” stylesheets
- **Direct:** is a “secure messaging” system for healthcare entities
- **API:** Application Programming Interface
- **FHIR:** Fast Healthcare Interoperability Resource



# What is the 21st Century Cures Act?

## **Empowering Patients with Their Health Record in a Modern Health IT Economy**

The patient is at the center of the 21<sup>st</sup> Century Cures Act. Putting patients in charge of their health records is a key piece of patient control in health care, and patient control is at the center of HHS' work toward a value-based health care system.

The ONC Cures Act Final Rule implements interoperability requirements outlined in the Cures Act. Patients need more power in their health care, and access to information is key to making that happen.

<https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>

# Overview

*Putting the patient first* in health technology enables the healthcare system to deliver:

- Transparency into the cost and outcomes of their care
- Competitive options in getting medical care
- Modern smartphone apps to provide them convenient access to their records
- An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice

***Congress passed the Cures Act with the intent that we can start to unravel the opaque schemes that are so common in American health care today.***



# Who Does it Impact?

- Patients
- Clinicians
- HIT Developers



# Patients

- HIPAA doesn't just address who *cannot* have access to PHI, it also empowers patients access to their own information
- Most patients who have access to information find it useful
- Many patients are not aware of their rights to access, but that is changing
  - 23% of Americans were unaware or didn't believe they had a right to an electronic copy of their medical record
  - 41% of Americans have never even seen their healthcare information





# What Clinicians Need to Know

- This is a federal regulation, it applies to **ALL** clinicians
- While the regulation was written by the Office of the National Coordinator (ONC), it will be enforced by the Office of the Inspector General (OIG) (both under the direction of Health & Human Services: HHS)
- Penalties for Information Blocking *for clinicians* are not yet finalized

## Patient's Ease of Access to Their Chart

The core goal of the health IT portion of the Cures Act is to provide patients with control of their health care and their medical record through smartphones and modern software apps. While considerations of privacy are very important, these choices should be made by the patient, not taken away by a doctor, hospital, or health IT developer under the narrative of “protecting patient privacy.”

# How to Approach Information Blocking

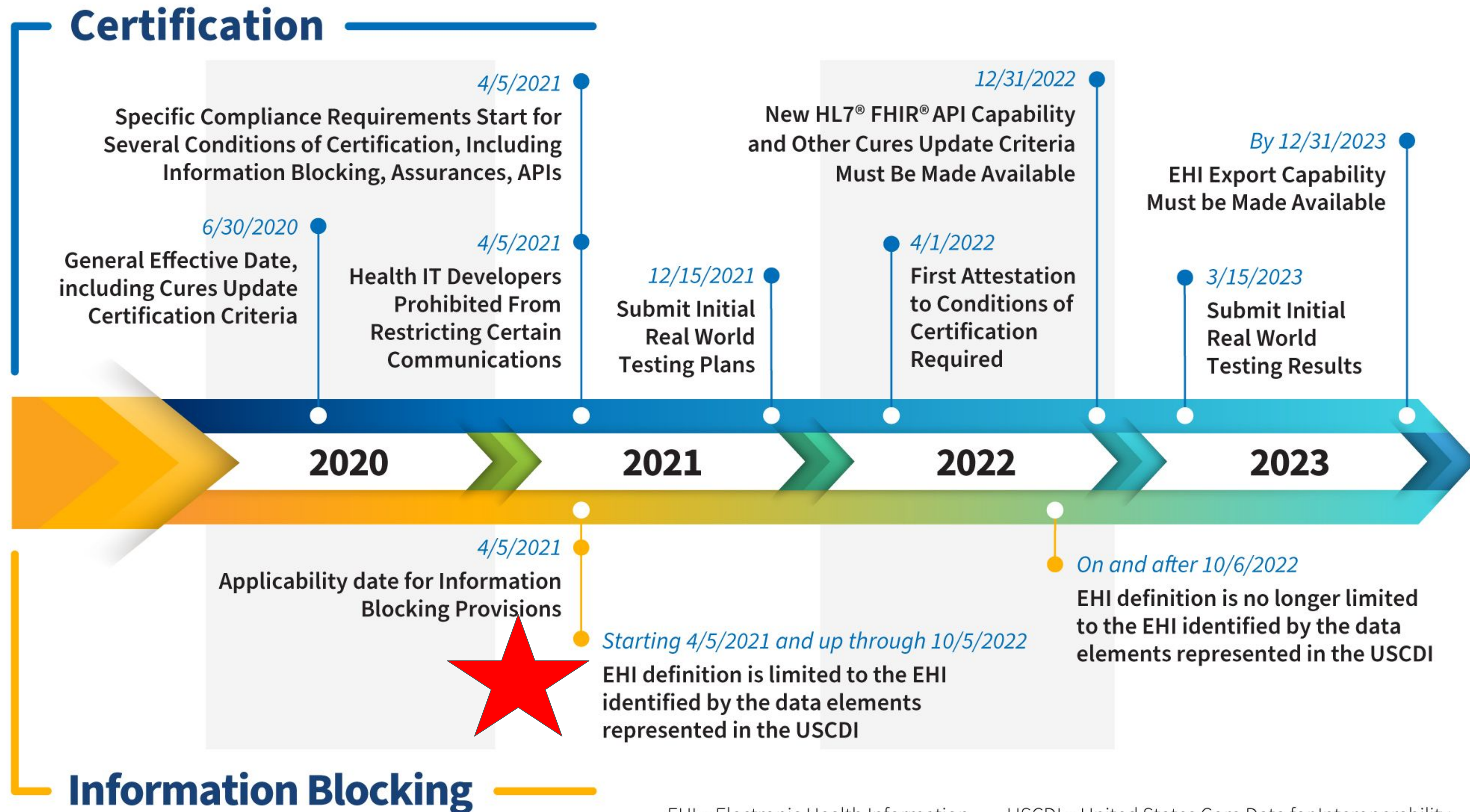
Privacy and Security are covered by **HIPAA**

Information Blocking is covered by the  
**21st Century Cures Act**

- BOTH require clinicians to
  - Review their policies/procedures and gaps regularly (ideally annually)
  - Have a written plan to address gaps
  - *Work* their plan to address issues identified/gaps



# Timeline



EHI = Electronic Health Information

USCDI = United States Core Data for Interoperability

# Whose Information is it Anyway?

- Research demonstrates improved outcomes for patients involved in their own healthcare
- Difficult for patients to be involved with limited/fragmented information
- 21st Century Cures Act:

*“Putting patients in charge of their health records is a key piece of patient control in health care, and **patient control is at the center** of HHS' work toward a value-based health care system.*

*The ONC Cures Act Final Rule implements interoperability requirements outlined in the Cures Act. **Patients need more power in their health care, and access to information is key to making that happen.**”*



# EHI (ePHI) and the 21st Century Cures Act

- Applies to any personal health information that is stored electronically
- May be in EHR, PMS or other electronic systems
- Must be shared with patients/patient representatives *in an electronic format if they request it that way*
- Can protect sensitive data in *very specific* circumstances (exceptions)
- Work to make sure you are protecting the “minimal amount” of information
  - Cannot say “I can’t show you your problem list, because I can’t hide your STI treatment”
  - Can say “I can’t show your STI problem on the problem list because I have no way to protect your legal right to privacy for adolescent care according to jurisdictional laws and prevent your parents from seeing it with my current technology”

# What Other Laws Apply?

- 21st Century Cures Act does **NOT** supersede HIPAA
- 21st Century Cures Act does **NOT** supersede state/regional/jurisdictional laws regarding privacy rights such as (but not limited to):
  - Substance Use Disorder
  - Adolescent Sexual and Reproductive Health Treatment
- Good place to start for jurisdictional laws:
  - Your State Medical Society
  - [Guttmacher Institute](#) for State Laws/Policies on broad range of issues related to sexual and reproductive health and rights



# Changing the way we Approach Sharing of Information

- Responding to requests for sharing of information
- Passive sharing of information

## What It Means for **Clinicians and Hospitals**



Making Patient  
Data Requests Easy  
and Inexpensive



Allowing  
Choice of  
Apps



Implementation



Improving  
Patient Safety

# Defining Information Blocking

- As of **April 5, 2021**, health care providers, health IT vendors, and health information exchanges may not engage in information blocking
- Information blocking is defined as **practices, policies, and actions** that restrict authorized **access, exchange, or use** of electronic health information (**AEU**)
- Inappropriate delays in information release may also be considered information blocking



# Access, Exchange, Use

- **Access:** the ability or means necessary to make EHI available for exchange, use, or both
- **Exchange:** the ability for EHI to be transmitted between and among different technologies, systems, platforms, or networks; and is inclusive of all forms of transmission such as bidirectional and network-based transmission
- **Use:** the ability for EHI to be understood and acted upon once accessed or exchanged. “Acted upon” includes the ability to read and write and is also bidirectional

# Where Do We Start?

- Designate an Information Blocking Compliance Officer (or team lead) for your practice
- Make ***time*** for the Information Blocking Compliance Officer to become informed and educated about the 21st Century Cures Act
- Have the Information Blocking Compliance Officer make a presentation to your entire practice team so all team members are aware of this mandatory federal regulation



# What Next?

- Commit to understanding how your current technology can/cannot protect sensitive information
- Document how patients currently request information and how you provide it
- Start documenting tomorrow in a way that allows confidence in sharing of information
  - Protect sensitive information correctly when you can **AND**
  - Check/update every chart you touch for accuracy
  - Add meaningful start/end dates to problems, meds, etc

*There is no longer a chance to “clean up the chart” before you release records...they are likely being shared and you aren’t even aware.*

# Guiding Principles Example

- Clinical Information should be as available as possible while respecting legal limitations.
  - Most practices will accomplish through a patient portal
  - Needs to be an “electronic” method of sharing
  - Could be an [API](#) that allows sharing (often through [FHIR](#) standards)
- Ideal portal sharing:
  - Parents/proxies should have access to their child’s non-sensitive information
  - Adolescents should have access to their information including sensitive information (with parental consent?)
  - Until the above can be supported through technology, alternative ways to release information safely should be sought



# Empowered Patients

- Significant efforts underway empowering patients, outlining their rights and how they can request access to their information
- Need to be aware of what health systems and others around you are doing
- One of the goals is to allow patients access to their records so they can give information to a specialist of their choice ***or transfer their records from one PCP to another without specific request***

21st Century Cures Act

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Power to the Patient: Our Record, Our Right, Our Choice

Steven Posnack | MARCH 12, 2020



# Exceptions



**EXCEPTIONS THAT INVOLVE**  
not fulfilling requests to access,  
exchange, or use EHI



# 8

**EXCEPTIONS TO THE  
INFORMATION  
BLOCKING  
PROVISION**



**EXCEPTIONS THAT INVOLVE**  
procedures for fulfilling requests  
to access, exchange, or use EHI



# What Must Be Shared to Avoid Information Blocking?

- Until October 6, 2022, for the purposes of the information blocking definition, EHI is limited to the data elements represented in the US Core Data for Interoperability **(USCDI) V1** standard adopted in the Final Rule
- Technology is advancing to support this deadline
- After 10/6/22 the definition of data to be shared is extended

# Empowered Pediatricians

- Health systems or organizations can no longer refuse or make it difficult for independent practices to get electronic data on their patients or we can file an “information blocking” grievance with the OIG starting in April
  - Includes large regional systems that refuse to share EHI with small practices unless you are part of the system
  - Includes labs that don’t want to create an electronic interface with you unless you pay exorbitant fees
- Should reduce the time we spend hand transcribing information we get from others about our patients
  - If the sender’s EHI is ‘messy and cluttered’ in their EHR, it will be equally messy and and cluttered when shared electronically



# USCDiv1



## Allergies and Intolerances

Represents harmful or undesirable physiological response associated with exposure to a substance.

Substance (Drug Class)  
Substance (Medication)  
Reaction



## Assessment and Plan of Treatment

Represents a health professional's conclusions and working assumptions that will guide treatment of the patient.

Assessment and Plan of Treatment



## Care Team Member(s)

The specific person(s) who participate or are expected to participate in the care team.

Care Team Member(s)



## Clinical Notes

Composed of both structured (i.e. obtained via pick-list and/or check the box) and unstructured (free text) data. A clinical note may include the history, Review of Systems (ROS), 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



## Goals

An expressed desired health state to be achieved by a subject of care (or family/group) over a period of time or at a specific point of time

Patient's Goals



## Health Concerns

Health related matter that is of interest, importance, or worry to someone who may be the patient, patient's family or patient's health care provider.

Health Concerns



## Immunizations

Record of an administration of a vaccination or a record of a vaccination as reported by a patient, a clinician, or another party.

Immunizations



## Laboratory

Tests  
Values/Results



## Medications

Medications



## Patient Demographics

First Name  
Last Name  
Previous Name  
Middle Name (including middle initial)  
Suffix  
Birth Sex  
Date of Birth  
Race  
Ethnicity  
Preferred Language  
Current Address  
Previous Address  
Phone Number  
Phone Number Type  
Email Address



## Problems

Information about a condition, diagnosis, or other event, situation, issue, or clinical concept that is documented.

Problems



## Procedures

An activity that is performed with or on a patient as part of the provision of care.

Procedures



## Provenance

The metadata, or extra information about data, that can help answer questions such as when and who created the data.

Author Time Stamp  
Author Organization



## Smoking Status

Classification of a patient's smoking behavior.

Smoking Status



## Unique Device Identifier(s) for a Patient's Implantable Device(s)

A unique numeric or alphanumeric code that consists of a device identifier (DI) and a production identifier (PI).

Unique Device Identifier(s) for a patient's implantable device(s)



## Vital Signs

Physiologic measurements of a patient that indicate the status of the body's life sustaining functions.

Diastolic blood pressure  
Systolic blood pressure  
Body height  
Body weight  
Heart Rate  
Respiratory rate  
Body temperature  
Pulse oximetry  
Inhaled oxygen concentration  
BMI Percentile (2 - 20 years)  
Weight-for-length Percentile (Birth - 36 Months)  
Head Occipital-frontal Circumference Percentile (Birth - 36 Months)



# What is Proposed in v2

## Allergies and Intolerances

Represents harmful or undesirable physiological response associated with exposure to a substance.

Reaction  
Substance (Drug Class)  
Substance (Medication)

## Assessment and Plan of Treatment

Represents a health professional's conclusions and working assumptions that will guide treatment of the patient.

Assessment and Plan of Treatment

## Care Team Member(s)

The specific person(s) who participate or are expected to participate in the care team.

Care Team Member(s)  
Provider Identifier   
Provider Name 

## Clinical Notes




Composed of both structured (i.e. obtained via pick-list and/or check the box) and unstructured (free text) data. A clinical note may include the history, Review of Systems (ROS), 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  
Procedure Note  
Progress Note

## Diagnostic Imaging

Diagnostic Imaging Narrative  
Diagnostic Imaging Order   
Diagnostic Imaging Report 

## Encounter Information

Encounter Diagnosis   
Encounter Time   
Encounter Type 

## Goals

An expressed desired health state to be achieved by a subject of care (or family/group) over a period of time or at a specific point of time

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Immunizations

## Laboratory

Laboratory Report Narrative  
Pathology Report Narrative  
Tests  
Values/Results

## Medications

Medications

## Patient Demographics

Birth Sex  
Current Address  
Date of Birth  
Email Address  
Ethnicity  
First Name  
Last Name  
Middle Name (including middle initial)  
Phone Number  
Phone Number Type  
Preferred Language  
Previous Address  
Previous Name  
Race  
Suffix

## Problems

Information about a condition, diagnosis, or other event, situation, issue, or clinical concept that is documented.

Date of Diagnosis   
Date of Resolution   
Problems

## Procedures

An activity that is performed with or on a patient as part of the provision of care.

Procedures

## Provenance

The metadata, or extra information about data, that can help answer questions such as when and who created the data.

Author Organization  
Author Time Stamp

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Diastolic blood pressure  
Head Occipital-frontal Circumference Percentile (Birth - 36 Months)  
Heart Rate  
Inhaled oxygen concentration  
Pulse oximetry  
Respiratory rate  
Systolic blood pressure  
Weight-for-length Percentile (Birth - 36 Months)



# What NOT to Worry About

- That April 5th someone is going to report you for information blocking and you will be fined millions of dollars
- That everything has to be in place and perfect by April 5th

***BUT.....***



# How are Pediatricians Helping?

- AAP's Council on Clinical Information Technology (COCIT) in contact with the ONC to get pediatric clarification
- Several pediatricians among a national workgroup "PP2PI" (Protecting Privacy to Promote Interoperability)
- Helping to define workflows for organizations
- Commenting on [USCD1v2 proposed data set](#)

Comments will be accepted until April 15, 2021, on the main [Draft USCDI v2 page](#) or on individual data class or data element pages. ONC will consider these comments and recommendations and begin preparing the final USCDI v2 for publication in July 2021.



# Resources

- ONC Information Blocking FAQs:  
<https://www.healthit.gov/curesrule/resources/information-blocking-faqs>
- AMA Information Blocking Overview:  
<https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf>
- USCDIv1 details/updates:  
[https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final\\_0.pdf](https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf)
- Information Blocking Exceptions Cheat Sheet from CHIME (College for Information Management Executives):  
[https://chimecentral.org/wp-content/uploads/2020/06/061420\\_CHIME-Information-Blocking-Cheat-Sheet-FINAL-RULE1-1.pdf](https://chimecentral.org/wp-content/uploads/2020/06/061420_CHIME-Information-Blocking-Cheat-Sheet-FINAL-RULE1-1.pdf)
- Suzanne Berman, MD, FAAP's Information Blocking Guide (Dropbox link):  
<http://bit.ly/infoblocking>

# What is OP Doing to Assist Pediatricians?

- From user 1, day 1, OP has always allowed pediatricians to granularly protect sensitive information including
  - Problem List items
  - Medications
  - Lab results
  - Notes
  - Parts of notes
  - Survey results
- Engaging our community of pediatricians on best practices regarding safely sharing information using OP tools and partner tools (such as the IntelliChart patient portal and Direct Messaging)