

# Sutter Health's Anti-Information Blocking Regulation Compliance

Updated as of 11/20/2020



# What is the Cures Act?

## 21<sup>st</sup> Century Cures Act:

Interoperability, Information Blocking, and the ONC Health IT Certification Program

The Office of the National Coordinator for Health Information Technology (ONC) published a [final rule](#) implementing components of the 2016 21<sup>st</sup> Century Cures Act.

This new federal regulation acknowledges the important role patients and their caregivers play on their care teams by requiring healthcare providers to electronically release most clinical notes and test results to patients/proxies.



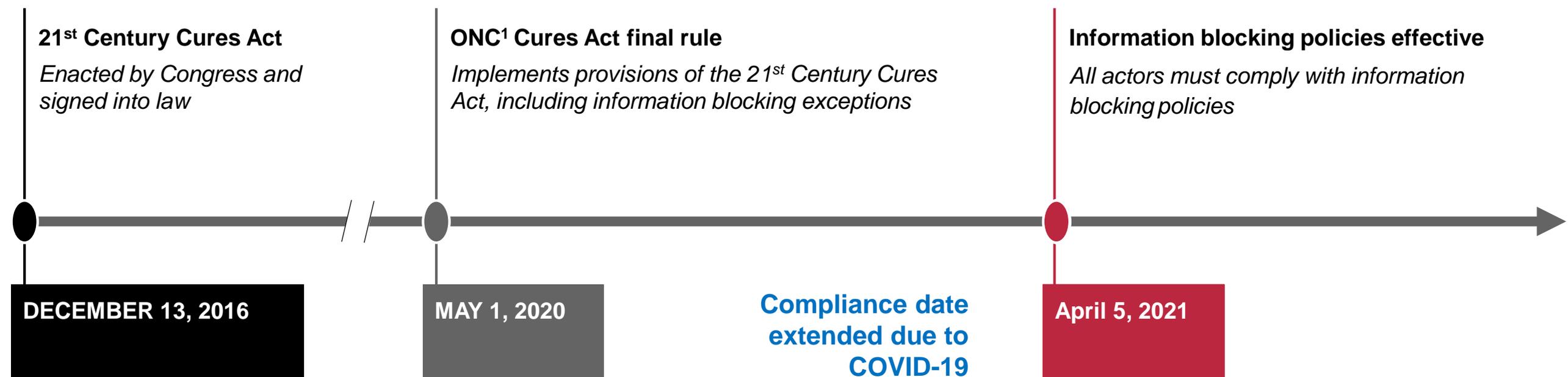
# What is information blocking?

“

A practice that is likely to interfere with access, exchange, or use of electronic health information... The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking”

*21<sup>st</sup> Century Cures Act*

## Timeline for information blocking policies



# Types of Actors

## Sutter Health falls under the rule's definitions of a *Provider* and a *Health Information Exchange/Network*



### Provider

“Defined in section 3000(3) of the Public Health Service Act (PHSA).”

*The term ‘health care provider’ includes 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, a pharmacist, a pharmacy, a laboratory, a physician, a practitioner, a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization, a rural health clinic, a covered entity under section 340B, a therapist, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.*



### IT developer

“An individual or entity, other than a health care provider that self develops health IT for its own use, that develops or offers health information technology and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj–11(c)(5) (ONC Health IT Certification Program).”



### HIE/HIN

“An individual or 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 EHI:

(1) among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and

(2) that is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.”

# Consequences for non-compliance

## Actors may face Civil Monetary Penalties up to \$1 Million per violation

### FINANCIAL

The information blocking provision holds accountable those who restrict access to electronic health information. Federal agencies can investigate allegations of information blocking, and violators could face penalties or other disincentives.

**Civil and monetary penalties for non-compliance delayed until April 5, 2021.**

### IMPACT ON PATIENT CARE

Information blocking restricts patients' access to the data that they need to better understand and engage in their health care. It also stifles innovation and makes it harder for health systems to improve care delivery and efficiency.

# ONC Announces Delay Oct 29, 2020

Sutter Health goes live on Open Notes & Results Release the same day

**On October 29, 2020, ONC announced an interim final rule in which ONC is extending the initial compliance date to April 2021 and timeframes for information blocking and the ONC Health IT Certification Program due to the COVID-19 Pandemic.**

*Sutter is well positioned and eager to embrace greater transparency and information access for our patients*

## **New interim final rule changes:**

- Extends applicability date for the Information Blocking provisions.
- Extends compliance dates in the ONC Health IT Certification Program and Conditions and Maintenance of Certification requirements for health IT developers.
- Makes changes to the Program by updating standards and clarifying regulatory text for specific certification criteria.

# What data is required to be shared ?

## US Core Data For Interoperability



<b>Allergies and Intolerances *NEW</b> <ul style="list-style-type: none"> <li>Substance (Medication)</li> <li>Substance (Drug Class) *NEW</li> <li>Reaction *NEW</li> </ul>	<b>Clinical Notes *NEW</b> <ol style="list-style-type: none"> <li>Consultation Note</li> <li>Discharge Summary Note</li> <li>History &amp; Physical</li> <li>Imaging Narrative</li> <li>Laboratory Report Narrative</li> <li>Pathology Report Narrative</li> <li>Procedure Note</li> <li>Progress Note</li> </ol>	<b>Patient Demographics</b> <ul style="list-style-type: none"> <li>First Name</li> <li>Last Name</li> <li>Previous Name</li> <li>Middle Name (incl. middle initial)</li> <li>Suffix</li> <li>Birth Sex</li> <li>Date of Birth</li> <li>Race</li> <li>Ethnicity</li> <li>Preferred Language</li> <li>Current Address *NEW</li> <li>Previous Address *NEW</li> <li>Phone Number *NEW</li> <li>Phone Number Type *NEW</li> <li>Email Address *NEW</li> </ul>	<b>Smoking Status</b>
<b>Assessment and Plan of Treatment</b>	<b>Goals</b>	<b>Problems</b>	<b>Unique Device Identifier(s) for a Patient's Implantable Device(s)</b>
<b>Care Team Members</b>	<b>Health Concerns</b>	<b>Procedures</b>	<b>Vital Signs</b> <ul style="list-style-type: none"> <li>Diastolic Blood Pressure</li> <li>Systolic Blood Pressure</li> <li>Body Height</li> <li>Body Weight</li> <li>Heart Rate</li> <li>Respiratory Rate</li> <li>Body Temperature</li> <li>Pulse Oximetry</li> <li>Inhaled Oxygen Concentration</li> <li>BMI Percentile (2-20 Years) *NEW</li> <li>Weight-for-length Percentile (Birth - 36 Months) *NEW</li> <li>Occipital-frontal Head Circumference Percentile (Birth - 36 Months) *NEW</li> </ul>
<p>For more info: <a href="http://HealthIT.gov/USCDI">HealthIT.gov/USCDI</a></p>	<b>Immunizations</b>	<b>Provenance *NEW</b> <ul style="list-style-type: none"> <li>Author Time Stamp</li> <li>Author Organization</li> </ul>	
	<b>Laboratory</b> <ul style="list-style-type: none"> <li>Tests</li> <li>Values/Results</li> </ul>	<b>Medications</b>	

Graphic source: Office of the National Coordinator for Health IT

# Information Blocking Exceptions

## Exceptions that involve NOT fulfilling requests to access, exchange, or use EHI



1. Preventing Harm Exception



2. Privacy Exception



3. Security Exception



4. Infeasibility Exception



5. Health IT Performance Exception

## Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI



6. Content and Manner Exception



7. Fees Exception



8. Licensing Exception

*Unless one of 8 exceptions apply, information must not be blocked.*

# What Providers can expect when composing clinical notes

1. The Epic standard button will be configured and defaulted to 'Share w/ Patient'
2. Clinicians will have the ability to block individual notes in the patient's chart if they meet the very restrictive federal criteria for such blocking .
  - This can be done by unselecting the 'Share w/ Patient' button
3. The reason specific exception criteria for blocking a note should be documented.
  - This should be done using the new system SmartPhrase (**.MYNOTESHIDE**) that allows providers to select the Information Blocking Exception criteria that applies to the note.

This note is not being shared electronically in My Health Online with the patient for the following reason:

{SH BLOCKED NOTE REASONS:133484}

- 1 To prevent harm: Healthcare professional reasonably believes that blocking this note will directly and substantially reduce a risk of harm to the life or physical safety to the patient, and/or other specific individual(s).
- 2 To respect privacy: The patient or proxy has requested that this information not be shared.
- 3 Promise of confidentiality: Information in this note was obtained from a non-healthcare provider who was promised confidentiality in exchange for disclosing the information and if it was disclosed their identity would be revealed.
- 4 The information in this note is compiled in order to be used in a civil, criminal, or administrative action/proceeding. Please consult with your local risk officer/resource before selecting this option.
- 5 California Health and Safety Code §123148. A health care professional has been unable to orally discuss test results within this note prior to its release. Test results must be related to (1) HIV antibodies, (2) the presence of antigens indicating a hepatitis infection, (3) abusing the use of drugs, or (4) processed tissue revealing a malignancy.

# Additional Exceptions: State Law

## Test Results & California Privacy Regulations

**Pre 10/29/2020** at Sutter Health:

- Normal final test results released next day at 6am
- Abnormal test results released 3 days later
- California Sensitive Test Results are not released

**As of 10/29/20, we release normal and abnormal results immediately except those addressed in California Privacy Regulation**

1. HIV antibody test results (positive or negative), unless an HIV test subject is anonymously tested and posted without identifiers  
→ *Manual Release only*
2. Presence of antigens indicating a hepatitis infection  
→ *Normal results release automatically; abnormal results will require manual release*
3. Abusing the use of drugs.  
→ *Normal results release automatically; abnormal results will require manual release*
4. Test results related to routinely processed tissues, including skin biopsies, Pap smear tests, products of conception, and bone marrow aspirations for morphological evaluation, if they reveal a malignancy.  
→ *Manual release only for all cytopathology and results of imaging tests that include a biopsy*

# Our approach to compliance

Information now available to Sutter Patients

## What does this mean for My Health Online?

On 10/29/2020 we made most clinical notes and test results available to patients via MHO.

## How do patients access historical notes?

Historical notes are still available through historic HIM Release of Information request process

## What about other applications hosting EHI?

We are in process of evaluating all applications across surgical hospitals, ASCs, SCAH and Kahi, in addition to IS-hosted applications for compliance by April, 2021.

### MHO Open Notes

- Release 8 clinical note types, prospectively
- Include notes from all care settings and authors: acute, ambulatory, surgical, behavioral health, nursing, etc.
- *Historical* Notes are not being released immediately through MHO, but are still available upon request through HIM Release of information request

### MHO Results Release

- Immediate release – Includes Lab and Imaging reports
- No provision for delaying release or withholding results unless release is *prohibited by law* or covered by an *exception*
- *Historically blocked* results will be available for manual release by clinicians

# Sutter Health's Open Notes & Results Release

## Resource Site

- Extensive FAQs - Providers, nursing, ancillary, operational teams
- Overview of Information Blocking Exceptions
- Presentation materials
- Clinician & Leader Messages
- Know-Do-Share and Epic EHR Tip Sheet documents
- Care Team Questions: **clinicians@sutterhealth.org**

**<https://tinyurl.com/sutteropen>**

# Questions



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# APPENDIX

# What do nurses need to know about Results Release?

## Releasing Sensitive Results

Manually releasing / retracting sensitive results that patients do not want shared is available to both nurses, ancillary teams, and providers

- Ambulatory nurses already release results and will continue on 10/29
- Inpatient nurses currently do not release results

## Workflow Recommendation

- A new results release workflow will be available on 10/29 within the Sutter ehr
- Inpatient nurses should not release results to the patient
- The nurse will let the provider know if a patient requests sensitive results be released or retracted
- It is up to the provider or advanced clinician to go into the Results Activity and release or retract the result

# Hot Topic: Care Team's Names

## Care Team Names

- Release specific (first and last) Care Teams names (currently also available through HIM ROI)

## What is available in MHO?

- MHO does not show inpatient care teams names within the CareTeam section (only ambulatory providers show today)
- Inpatient Care team names will show within each progress, procedure, telephone and Care Team note types and any electronic information that will be shared 10/29.
- As a reminder, all electronic health information (EHI) by May 2022

## MY CHART Bedside:

- Care Team names are currently available
- Planned expansion of My Chart Bedside across Sutter Health

# Team Structure

## Steering Committee (Bi-Weekly)

**Sponsor**  
Bill Isenberg MD, Exec Sponsor

**Pacesetters**  
Danielle Reno, MHA, Pacesetter  
Steven Lane MD, Pacesetter  
Howard Landa MD, Pacesetter

**Project Management**  
Pam Beeuwsaert – Project Manager

**Focus Group Leaders**  
Veena Jones MD, MHO/Open Notes  
Albert Chan MD, VP Digital Patient Experience  
Jane Schulze, HIM  
Kevin Chen MD, Bay Foundation  
Mike Conroy MD, Valley Foundation  
Bryanna Gallaway, Patient Experience  
Mary Schramke, Patient Family Advisor  
Nancy Turner, Communications  
Lisa Knowles, Compliance  
Kiren Gurai, OGC/Privacy Info Security  
Jeremy Harris, OGC/Privacy Info Security  
Doug Angove, IS Integration  
Sheli Page, IS Applications  
Tom Carlson, IS Applications  
Christine Jensen, SHP  
David Nessim MD, SCC  
Julia Adler MD, Mental Health

## Proposed Focus Groups (Weekly)

<b>MHO/ Open Notes</b> Veena Jones, MD Tom Mitchell	<b>OGC</b> Jeremy Harris Jon Romvary	<b>HIM</b> Jane Schulze Gary Sweeney Maisha Weary Meghan Church	<b>Informatics</b> Howard Landa MD Arthur Sorrell MD Charu Puri MD Donna Woelfel Adam Davis	<b>Mental Health</b> Julia Adler MD	<b>SCC</b> David Nessim MD Cynthia Matsko
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<b>Compliance</b> Lisa Knowles	<b>OGC /Privacy Info Security</b> Jeremy Harris Kiren Gurai Amber Brown Hilary Isacson	<b>IS Integration</b> Joanna Washburn
<b>SHP</b> Christine Jensen	<b>IS Integration</b> Doug Angove Joanna Washburn Adam Davis MD Karen Williams Nithya Vijayaraghana	

<b>Communi- cations</b> Nancy Turner Bryan Gardner	<b>Bay/Valley Operations</b> Kevin Chen, Mike Conroy Kelvin Lam Ash Gokli Physicians as needed	<b>Patient Experience</b> Bryanna Gallaway Soumitra Gaopande (PFA)	<b>Marketing</b> Theresa Massie Vince Jocson Christina Szeto Jennifer Crow	<b>Informatics</b> Arthur Sorrell MD Charu Puri MD
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**IS**  
Tom Carlson,  
Sheli Page  
Doug Angove  
Joanna Washburn

# MHO Teen Enrollment & Access to Features

- Parental consent is required.
- Teens can only enroll in-person (except during COVID-19).

My Health Online Features by User Type					
Feature	Proxy to Child (<12)	Patient (Self and/ or Teen)	Proxy to Teen(12-17) / Young Adult (18-25)	Proxy to Adult (>18)	Proxy to patient any age with diminished capacity
Clinical Messaging	Y	Y	Y*	Y	Y
Confidential Messaging	Y	Y	Y*	Y	Y
Tests Ordered / Test Results	Y	Y	N	Y	Y
AVS / Appointment Details	Y	Y	N	Y	Y
Rx Renewals	Y	Y	N	Y	Y
Auto-Pend Orders	Y	Y	N	Y	Y
Direct Scheduling	Y	Y	Y*	Y	Y
Appointment Requests	Y	Y	N	Y	Y
Immunizations	Y	Y	Y	Y	Y
OpenNotes	Y	N	N	Y	Y

*\*proxy can only schedule PCP appointment and message PCP for their teen*

# Latest Timeline from ONC



## New Applicability/Compliance Dates included in ONC Interim Final Rule

Information Blocking and the ONC Health IT Certification Program:

Extension of Applicability and Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule

