

21st Century Cures Act and Adolescent Confidentiality

Jesse Hackell, MD FAAP
Megan Maddocks, MBA
Jim Smith

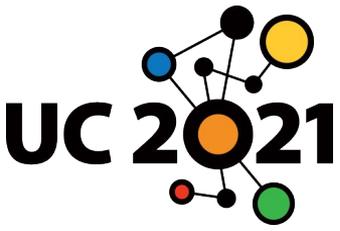


Session Goals

1. Review Information Blocking Definition
2. Open Notes
3. Case study
4. PCC EHR and adolescent confidentiality



21st Century Cures Act



What is Information Blocking?

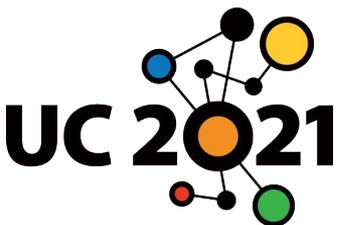
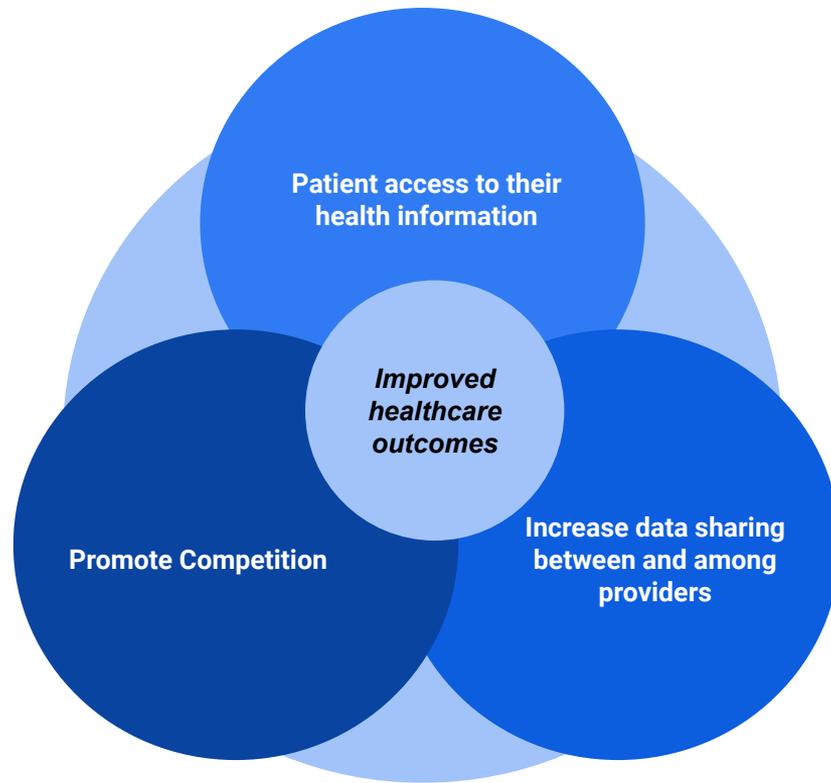
Information blocking is defined in the 21st Century Cures Act. In summary, information blocking is “a practice that...is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information,” unless such practice is required by law (e.g., HIPAA), or it meets an exception established through federal rulemaking.



[42 U.S.C. § 300jj-52\(a\)\(1\).](#)



What is the intent of this regulation?



Does the ONC Cures Act final rule require electronic health information (EHI) to be shared proactively?

“No. There is no requirement under the information blocking regulations to proactively make available any EHI patients or others who have not requested the EHI”.

The information blocking regulations center around responding to requests for EHI. Conversely, providers may also choose to share EHI proactively.

*Please see the Information Blocking FAQs page for complete question and answer:
<https://www.healthit.gov/curesrule/resources/information-blocking-faqs>*



Penalties Structure

The ONC Final Rule compliance date is **April 5, 2021**, however, the penalty structure is still in development...

Actor	Enforcement Agency	Penalties and Start Date
Healthcare Providers	Centers for Medicare and Medicaid	Penalties: TBD Start Date: TBD
Certified Health IT Vendors	Office of the Inspector General	Penalties: up to \$1million per infraction Start Date: TBD
Health Information Exchanges and Health Information Networks	Office of the Inspector General	Penalties: up to \$1million per infraction Start Date: TBD



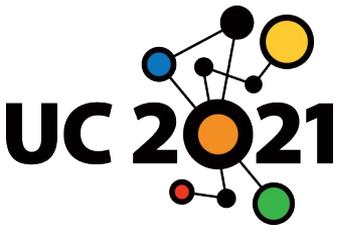
Information Blocking Exceptions

ONC defined eight exceptions when it may be appropriate to NOT comply with the information blocking rule, or alter the way in which EHI is accessed, exchanged, or used

- Exceptions that involve not fulfilling requests:
 - Preventing Harm
 - Privacy
 - Security
 - Infeasibility
 - Health IT Performance
- Exceptions and procedures for fulfilling requests to access, use, or exchange EHI:
 - Content and Manner
 - Fees
 - Licensing

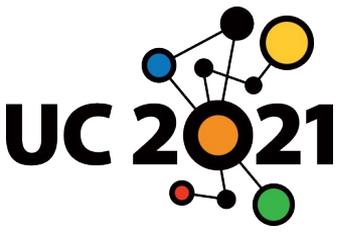


Open Notes



Open Notes Basics

- Open Notes is administrative; it is not an application used to share clinical information
- Open Notes, and the sharing of full clinical note types has found to increase patient understanding of and participation in their care, yet adolescent confidentiality remains a concern¹
- “Clinicians must ensure that confidential information is properly protected and ensure that the adolescent’s rights are respected”²



¹Chethan Sarabu, Natalie Pageler and Fabienne Bourgeois Pediatrics October 2018, 142 (4) e20180601; DOI: <https://doi.org/10.1542/peds.2018-0601>

²Fabienne C. Bourgeois, Catherine M. DesRoches and Sigall K. Bell Pediatrics June 2018, 141 (6) e20172745; DOI: <https://doi.org/10.1542/peds.2017-2745>

Adolescent Confidentiality Case Study



Open Notes in Practice

- Much in the regulations which is helpful/useful/empowering
- Clearly pediatricians were not involved in writing the regs
- Problematic for newborns, adults with disabilities, elderly
- ...and adolescents have unique issues



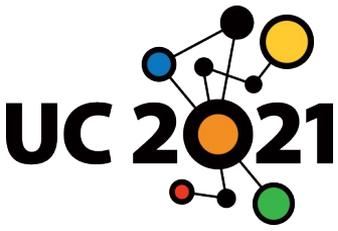
A Hypothetical, but not Uncommon, Patient

- 16 year old female patient
- Father out of job, money tight
- Asthma—has nighttime cough, occasional wheezes
- Has relief and controller inhalers, not using
- PHQ-9—moderate depression, not suicidal
- Multiple sexual partners, unprotected on occasion, strangers (money)
- Lab--+ chlamydia
- Grades in school (10th grade) C's and D's this year, down from A's
- Binge drinking alcohol once—led to sexual assault



Assessment and Management

- Discuss asthma, proper use of controller and relief inhalers
 - Problem list
 - Medication list
- Depression - refer to mental health counselor, start SSRI
 - Problem list
 - Medication list
 - Referral plan
- At risk sexual behavior
 - Problem list
 - Referral
 - Counseling



Assessment and Management, continued

- Chlamydia treatment
 - Problem list
 - Medication list
 - Counseling
- Sexual assault
 - Counseling
 - Referral
- SDOH
 - Community services referral
- Substance abuse
 - Counseling
 - Possible medication list
- And...everything is documented in your final note



Specific EHR Datapoints

- PHQ9
- Lab
- Social History
- Medication list
- Visit note

Under Open Notes, EVERYTHING here is supposed to be made available...but to whom?

Non-sensitive - to parent and teen

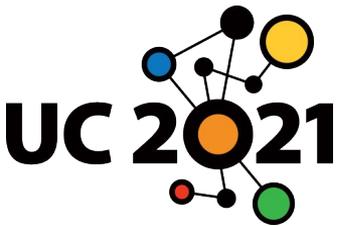
Sensitive - adolescent's confidence is protected by statute



How to Deal with these Datapoints

- Labs - probably easiest. Flag each test by CPT as shareable/not shareable
- Screenings - mostly mental health, and should be marked non-sharable
- Social history - needs segmentation (school vs. substance vs. sexuality). Each datapoint could be flagged
- Mental health - should not be shared. But where does it reside?
- Medication list - should each medication be marked appropriately when prescribed? Some meds have two types of uses

Does your EHR Even have these abilities?



The Visit Note

- Pulls information from a variety of templates, combines it into a narrative note
- Items marked non sharable—do they get pulled, and if not, where do they reside? (Note PHQ9 done, but with no results?)
- Creation of two different notes??? (One to share, one confidential)
- Medication list—clues to conditions which should be confidential
- Shadow chart
- Chart with obvious redactions



Practical Aspects

- This CAN be managed by careful input by clinician
- But at what cost/burden?
- Ideally, segmentation of data would be done in the background, with provider oversight/editing
- Requires extreme granularity in the EHR



Payment - the ULTIMATE Practical Aspect

- Medicaid - may actually be easier to address (no EOB)
- Private insurance
 - Interests of person paying for insurance
 - Confidentiality interests of the patient
 - Individual payer policies

An EOB sent to someone who does not have access to the medical record can trigger a demand for the record, which is protected

Direct impact on the provider who is caught in the middle

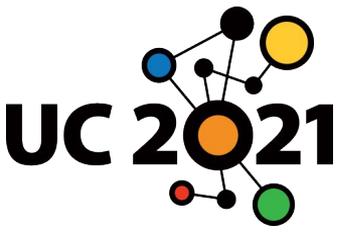


The Ideal Situation

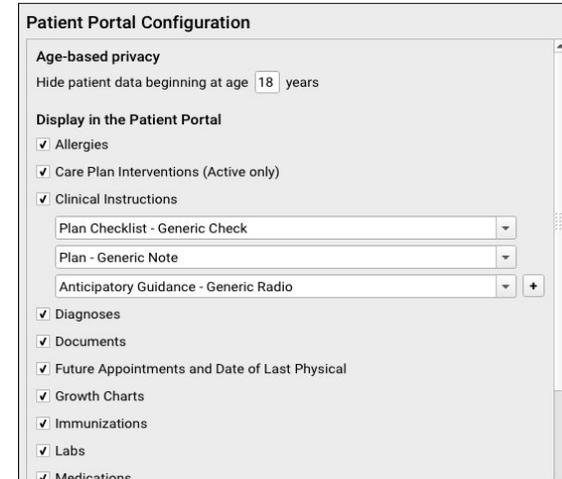
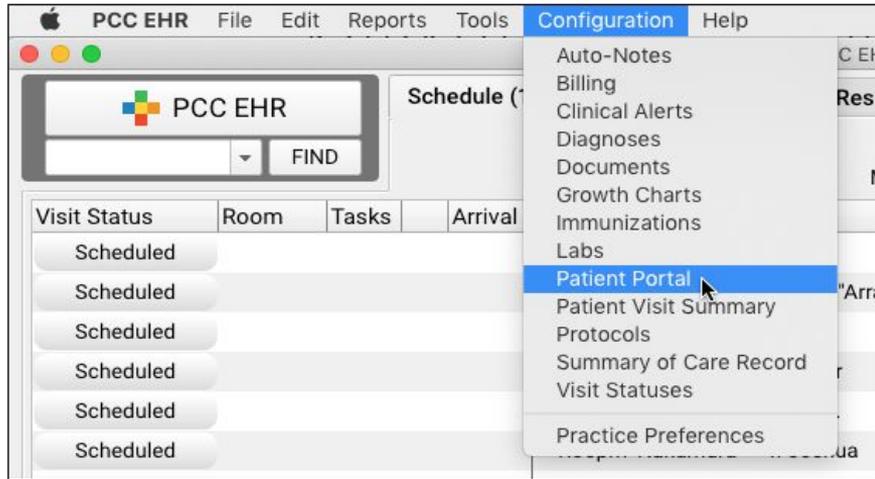
- Perfectly segmented data in the chart/note
 - Controlled portal access
 - Is there a public chart and a “shadow” chart
- Protected information
- But accessible to other HCPs who may be treating the patient
 - And who then must assume the responsibility for confidentiality of medical information, even if THEIR information is not protected
 - Pharmacists
 - Social services
 - Payers



PCC EHR

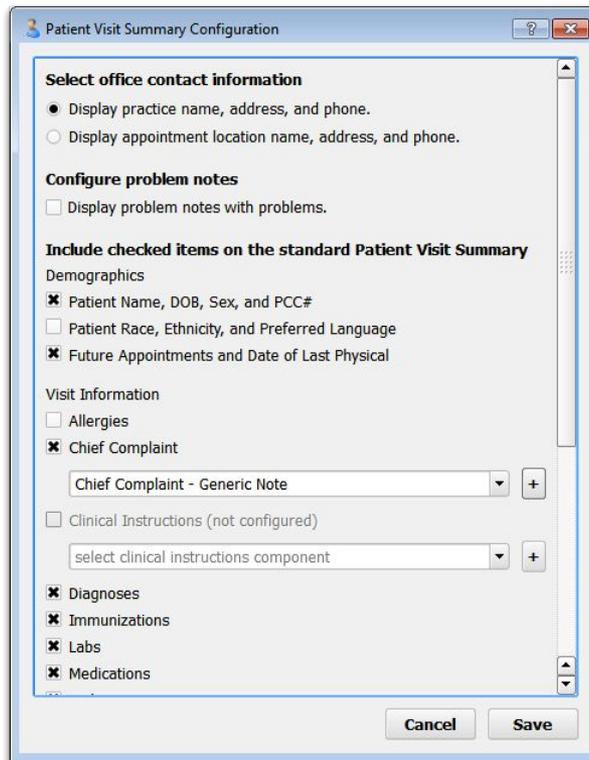
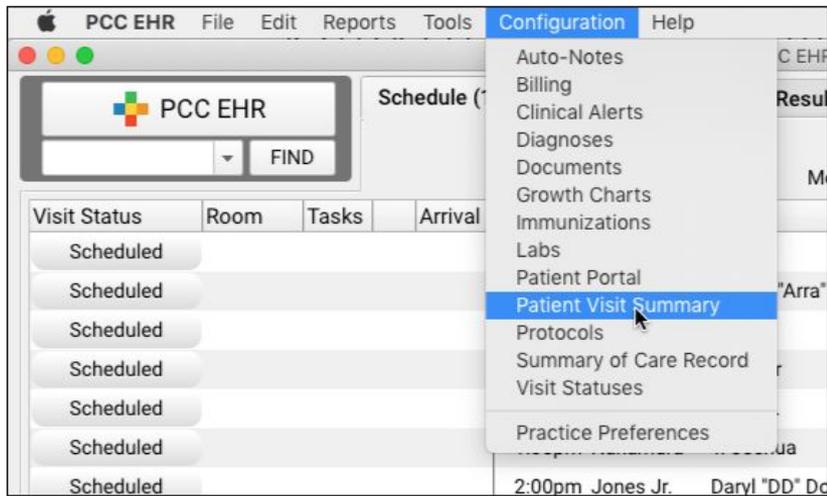


Patient Portal Configuration



- Specify the data elements you want to share in the portal
- Holding back ALL diagnoses, medications, labs, screenings, etc makes you more vulnerable to Information Blocking allegations

Visit Summary Configuration



- Specify the default data elements to share in the Patient Visit Summary generated from the EHR
- Confidential orders will not appear

Clinical Instructions

Patient Portal Manager

Administration Configuration

Configuration

Age-based privacy
Hide patient data beginning at age years

Display in the Patient Portal

- Allergies
- Care Plan Interventions (Active only)
- Clinical Instructions
 - Additional History - Generic Check
 - Plan Checklist - Generic Check
 - Anticipatory Guidance Discussed - Generic Radio
- Diagnoses

- You can add any generic chart note component to the Clinical Instructions, and they will appear.



Diagnosis Configuration

Diagnosis Configuration
Search Filter: pregnant

Favorite	Allergy	Family Hx	Diagnosis
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal pain in early pregnancy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal pain in pregnancy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Antenatal ultrasound confirms intrauterine pr...
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Finding of shape of pregnant abdomen
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	First trimester pregnancy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Galactorrhea not associated with childbirth
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Gravida 2
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	History of recurrent miscarriage - not pregnant
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Intends to continue pregnancy
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MRSA carriage

Edit Diagnosis
Description: 🚫 First trimester pregnancy

- Include on Patient Reports
- Apply historically throughout all patient charts
- Favorite - available for selection in the Diagnoses and Problem List components
- Allergy - available for selection in the Allergies component
- Family Hx - available for selection in the Family Medical History component

Buttons: Cancel Save

Callout 1: Unchecking this box will hide the diagnosis by default

Callout 2: Checking this box will retroactively hide all instances of the diagnosis

- Use Diagnosis Configuration Tool to make a diagnosis hidden by default

Lab Configuration

Lab Configuration

Lab Orders Common Tests Lab Facilities

Lab Orders

Name	Type	Default Lab Facility
▶ Hepatitis B surface antigen	Lab Order	
▶ HEPATITIS B SURFACE ANTIGEN W/REFL CONFIRM Elab	Lab Order	Quest Diagnostics
▶ HEPATITIS C ANTIBODY Elab	Lab Order	Quest Diagnostics
▶ Hepatitis Panel	Snap Lab Order	n/a
▶ HgA1C	Lab Order	
▶ HIV	Lab Order	
▶ HIV AB, HIV 1/2, EIA, WITH REFLEXES Elab	Lab Order	Quest Diagnostics
▶ HIV ANTIBODY, HIV 1, WESTERN BLOT Elab	Lab Order	Quest Diagnostics
▶ HLA B27	Lab Order	
▶ HPV DNA (HIGH RISK) Elab	Lab Order	Quest Diagnostics
▶ IgA antibody	Lab Order	
▶ Influenza A	Lab Order	
▶ Influenza A/B	Lab Order	Use Appointment Location
▶ Influenza B	Lab Order	

Unchecking this box will hide the lab order by default.

Lab Configuration

Lab Orders Common Tests Lab Facilities

Edit Lab Order

Lab Order Name: HIV

Default Lab Facility: select a lab facility

Enable recording of Specimen Collection user, date and time

"Include on Patient Reports" will be selected when this order is issued

Allow this order to be Refused

Allow this order to be Contraindicated

SNOMED CT Procedure for reporting

[Add a Procedure](#)

E-lab Vendor Order Mapping (for automated results)

FAHC: select a FAHC order

LabCorp: select a LabCorp order

Cancel Save

- Use Lab Configuration Tool to make a lab order hidden by default

Confidential Notes

Protocol Configuration

Component Builder

Visit Components | Chart-wide Components

Component Name	Component Type	Attributes
Allergies	Allergy List	Reviewable
Care Plan	Care Plan	Reviewable
Communication Preferences	Communication Preferences	
Confidential Notes	Generic Chart-wide Note	Confidential
Family History	Generic Chart-wide Note	Reviewable
Family Medical History	Family Medical History	Reviewable
Medical History	Generic Chart-wide Note	Reviewable
Mental Health Notes	Generic Chart-wide Note	Confidential
Patient Demographics	Patient Demographics	
Problem List	Diagnosis List	Reviewable
Reminders	Generic Chart-wide Note	Reviewable
Social History	Generic Chart-wide Note	Reviewable

Edit Component

Component Name:

Component Type: generic chart-wide note

Confidential: Yes No

Reviewable in Visit: Yes No

- Generic chart-wide components can be added and made confidential
 - Include these within the Medical Summary or individual protocols



Direct Secure Messaging (DSM)

- DSM ([Direct Secure Messaging](#)) is secure email used for exchanging patient clinical data among clinicians
 - Only useful if you have the Direct address for other clinician and they also use the feature
- Send patient Summary of Care (C-CDA) and other documents to clinicians
- Receive Summary of Care, images or pdfs from other clinicians
- Not a required functionality within Info Blocking regulations



Clinical Document Exchange (CDE)

- Participate in [Clinical Document Exchange](#) to share patient clinical data with other clinicians within the national Carequality Network
- Responder Role (now available in PCC EHR):
 - Respond to requests from other organizations within the Carequality Network
 - Longitudinal Summary of Care is shared
- Initiator Role (now in pilot testing):
 - Request patient records from other organizations within the Network
 - Longitudinal and encounter-based Summaries of Care are typically shared



Not a required functionality within Info Blocking regulations

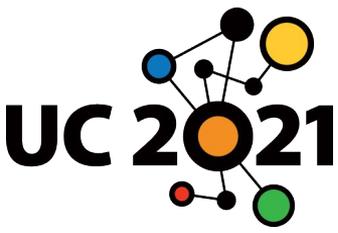
Session Takeaways

1. There will be more questions than answers, and we will continue the discussion
2. Unlike other patients, Adolescents' care leads to greater difficulties to comply with the regulations
3. Having written policies and guidance is important for providers, staff, and patients



What Questions Do You Have?

Questions posted in the Socio will be read aloud by moderator for the presenter to answer. Please post your questions in Socio now.



References

<https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

<https://www.federalregister.gov/documents/2020/11/04/2020-24376/information-blocking-and-the-onc-health-it-certification-program-extension-of-compliance-dates-and>

<https://www.federalregister.gov/documents/2020/04/24/2020-08451/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector>

ONC Cures Site: <https://www.healthit.gov/curesrule/>

ONC Cures Rule FAQs: <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>

ONC Cures Rule Fact Sheets: <https://www.healthit.gov/curesrule/resources/fact-sheets>



References

[OpenNotes: Toward a Participatory Pediatric Health System | American Academy of Pediatrics \(aappublications.org\)](#)

[The Views and Experiences of Clinicians Sharing Medical Record Notes With Patients | Electronic Health Records | JAMA Network Open | JAMA Network](#)

[Ethical Challenges Raised by OpenNotes for Pediatric and Adolescent Patients | American Academy of Pediatrics \(aappublications.org\)](#)



Later Viewing

This and all other UC2020 course recordings will be available for later viewing on [PCC's YouTube Channel](#)

