

*Information Blocking: What Physicians and
Physician Groups Need to Do Now*



Amy Murray and Russell Anderson

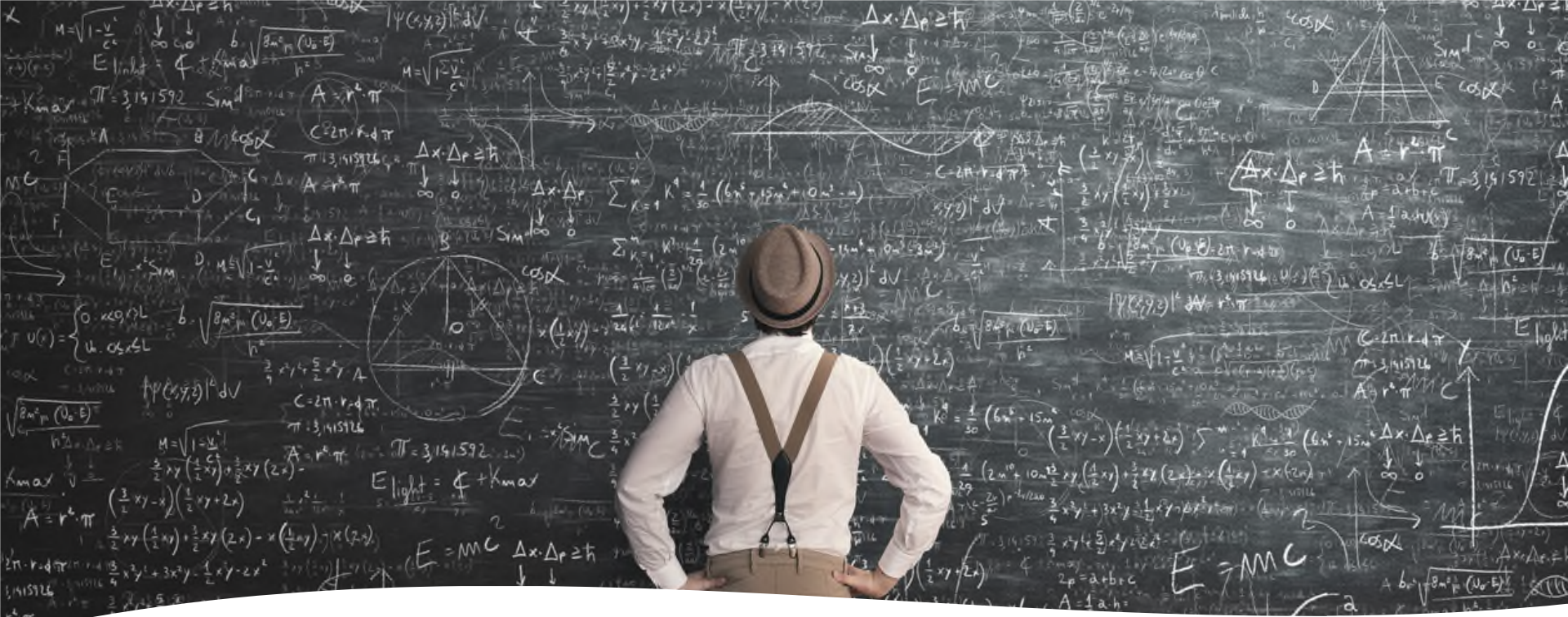
March 2nd, 2021

21st Century Cures Act

- Builds on Earlier Effort to Promote Interoperability
 - HITECH Act (2009)
 - “Meaningful Use” Incentives

- The 21st Century Cures Act—§ 4004
 - The term “information blocking” means a practice that—
 - (A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and...
 - (ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

- Leaves much to HHS
 - More precise definition of “information blocking” – mostly through exceptions
 - Penalties and enforcement



Putting the Pieces Together

- Office for the National Coordinator of Health IT (“ONC”)
- Centers for Medicare and Medicaid Services (“CMS”)
- Office for Civil Rights (“OCR”)

What is Information Blocking?

A practice that, except as required by law or covered by an exception, is **likely to interfere** with access, exchange, or use of electronic health information (EHI);

and

if the actor is a health care provider, **knows that such practice is unreasonable and likely to interfere with** access, exchange, or use of EHI.

Information Blocking Elements

- The individual/entity engaging practice is an “Actor”;
 - Health Care Providers
 - Health IT Developers of Certified Health IT
 - Health Information Networks/Health Information Exchanges
- The practice involves “EHI”;
 - April 5, 2021 to October 6, 2022 → data in the USCDI.
 - October 6, 2022 and forward → all ePHI that is part of patient’s electronic designated record set.
- The practice is likely to interfere with access, exchange, or use of EHI;
- The actor meets the knowledge standard;
- The practice was not required by law; and
- The actor’s practice does not meet the conditions of an exception.

United States Core Data for Interoperability (USCDI)

April 5, 2021

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment

- Assessment and Plan of Treatment

Care Team Members

- Care Team Members

Clinical Notes

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

Goals

- Patient Goals

Health Concerns

- Health Concerns

Immunizations

- Immunizations

Laboratory

- Tests
- Values/Results

Medications

- Medications

Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems

- Problems

Procedures

- Procedures

Provenance

- Author Time Stamp
- Author Organization

Smoking Status

- Smoking Status

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

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

Vital Signs

- 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)

Designated Record Set

- After October 6, 2022, the scope of covered EHI under the information blocking rule will expand to include the full electronic designated record set (DRS) as defined in HIPAA.
- Healthcare providers will be obligated to provide not only the USCDI information listed above, but also DRS data which includes:
 - medical & billing records about individuals maintained by or for a covered health care provider;
 - enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
 - other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals.

Other Considerations

- For Hospitals - as a new Condition of Participation, under the CMS rules, hospitals with compliant EHR systems must provide admission, discharge and transfer (ADT) event notifications to all providers primarily responsible for a patient's care.
- HIPAA – Still have requirement to provide patients access. Sixteen (and counting) access enforcement actions in the past 18 months.
- Remember that Information Blocking apply only to EHI, but the HIPAA access rules apply to paper records as well.

What Is Information Blocking?

- There are certain situations where interfering with access, exchange, or use of EHI will always implicate information blocking, related to:
 - Patient access
 - Treatment
 - Payment
 - Health care operations
 - Public health activities



What Is Information Blocking?

- Patient access: Providing patients with access to their EHI and the ability to exchange and use it without special effort.
 - Strong emphasis on ensuring patients have access to their own EHI, and are able to easily exchange and use their own EHI.
 - Consistent with HIPAA, pursuant to which patients have a strong right to access their own records.

What Is Information Blocking?

- Treatment: Ensuring that healthcare professionals, care givers, and other authorized persons have the EHI they need, when and where they need it, to make treatment decisions and effectively coordinate and manage patient care and can use the EHI they may receive from other sources.
 - **Key Note**: Releases of information that were “permitted” (and discretionary) under HIPAA are now **required** under information blocking.

What Is Information Blocking?

Did the actor interfere with the access, use, or exchange of data?

If yes, does it fall under an exception?



Exceptions to Information Blocking

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

- Prevent harm exception
- Privacy exception
- Security exception
- Infeasibility exception
- Health IT performance exception

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

- Content and manner exception
- Fees exception
- Licensing exception

Information Blocking Exceptions

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

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

Information Blocking Exceptions

- Preventing Harm Exception: Not information blocking if it is **reasonable and necessary to prevent harm to a patient or another person**, provided certain conditions are met (high bar).
 - Must hold a *reasonable belief* that the practice will substantially reduce a risk of harm.
 - Type of risk:
 - Safety issue
 - Perceived flaw in the data
 - Type of harm:
 - Danger to the person's life or physical safety
 - Practice must be no broader than necessary.

Information Blocking Exceptions

- Privacy exception: Not information blocking to **protect an individual's privacy**, provided one of four conditions is met.
 - 1) A legal precondition is not yet met (key).
 - 2) Denial of an individual's request for their EHI is consistent with 45 CFR 164.524(a)(1) and (2).
 - 3) Respecting an individual's request not to share information.
- Note: Must apply in a non-discriminatory manner
 - Either pursuant to a written policy, or
 - Based on an individual assessment of the circumstance.

Information Blocking Exceptions

- Security exception: Not information blocking to **protect the security of EHI**, provided certain conditions are met
- Practice must be:
 - Directly related to safeguarding the confidentiality, integrity, and availability of EHI,
 - Tailored to the specific security risk being addressed, and
 - Implemented in a consistent and non-discriminatory manner.
 - The practice must be based on a written policy, or a specific facts and circumstances determination.

Information Blocking Exceptions

- Infeasibility exception: Not information blocking to not fulfill a request for access, exchange, or use EHI because it is **infeasible**, provided certain conditions are met. Must meet one of the following conditions:
 - Uncontrollable events
 - Segmentation
 - Infeasible under the circumstances
- Must provide a written response to the requestor within 10 business days of the request, providing the reason(s) why the request is infeasible.

Information Blocking Exceptions

- Health IT performance exception: Not information blocking to take reasonable and necessary measures to make **health IT temporarily unavailable** or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided 1 of 4 conditions are met:
 - Maintenance or improvement of Health IT
 - Assured level of performance
 - Practices that prevent harm
 - Security-related practices

What Isn't Information Blocking?

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

- Content and manner exception
- Fees exception
- Licensing exception

Information Blocking Exceptions

- Content and manner exception (key):
 - **Content:** Not information blocking to limit the content of a response to a request to access, exchange, or use EHI, provided certain conditions are met.
 - April 5, 2021 to October 6, 2022 – only USCDI data elements need to be provided.
 - October 6, 2022 on – all ePHI that is part of the patient’s electronic designated record set must be provided.
 - **Manner:** Not information blocking to limit the manner in which a request to access, exchange, or use EHI is fulfilled, provided certain conditions are met.
 - An Actor must fulfill an information request in the manner requested, unless the Actor is technically unable to fulfill the request. If so, the Actor must provide the requested information in an alternative manner without unnecessary delay.
 - Note: Alternative manner order of priority applies.

Information Blocking Exceptions

- Fees exception: Not information blocking to **charge fees**, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.



Information Blocking Exceptions

- Licensing exception: Not information blocking to **license interoperability elements** for EHI to be accessed, exchanged, or used, provided certain conditions are met.
- Exception allows for the protection of the value of innovations and the charging of reasonable royalties to earn returns on investments.

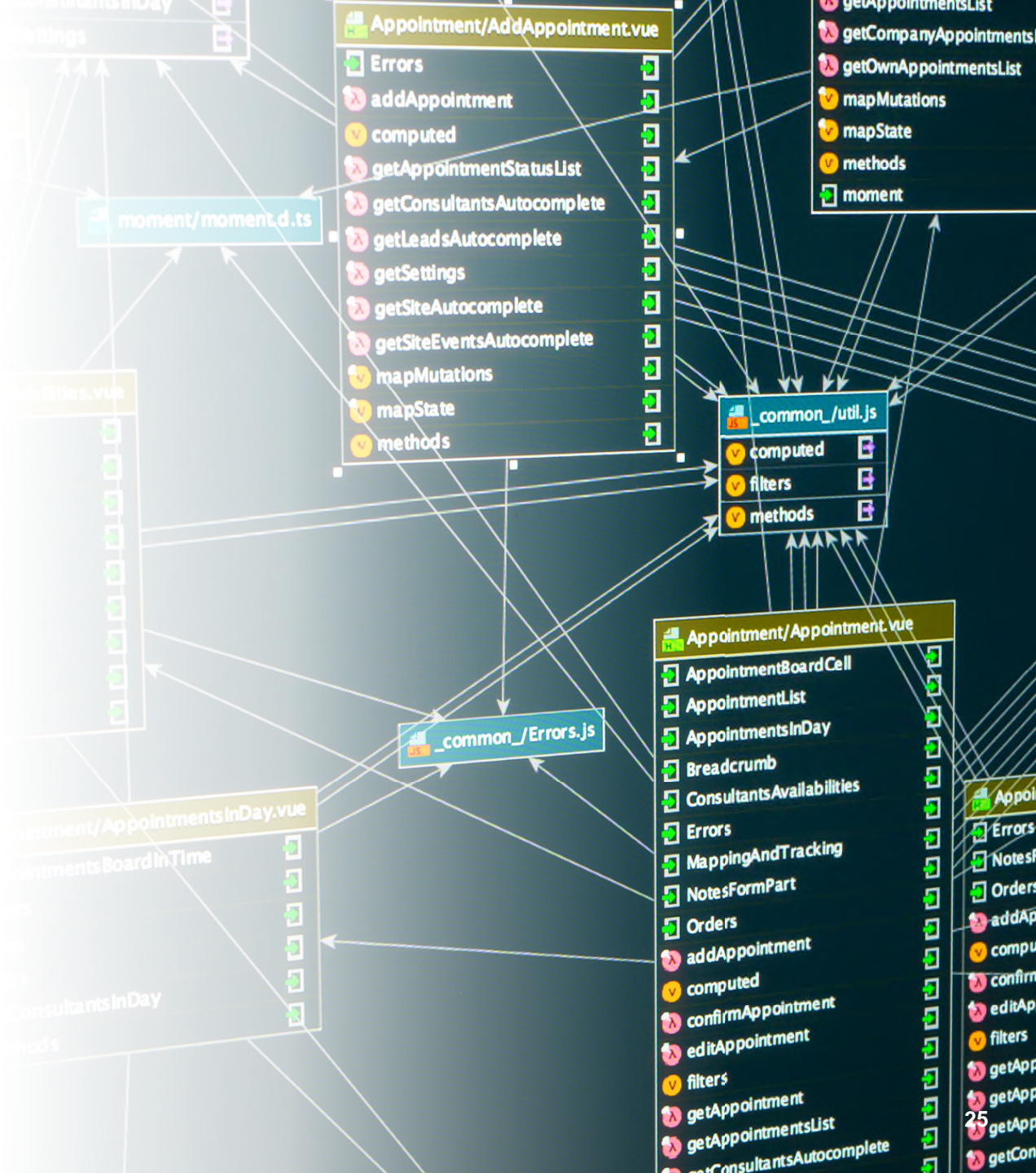
What Providers Need to Do

- Assemble resources – physicians, administration, IT and legal.
- Consider how patient information flows in your practice – to providers, to patients, to payers, to other stakeholders (e.g., patient family members). When do you provide that information? How do you provide that information? What steps/hurdles do you require?
- Information blocking is largely a question of proving a negative. Create an implementation plan for documenting how your practice will comply.



Evaluate Information Technology Systems

- Technical Standard - Fast Healthcare Interoperability Resources (FHIR) Health Level 7 (HL7) Standard
- Health care providers not required to upgrade to an EHR that uses this standard for APIs at this time.



Contractual Information Blocking

- Review vendor agreements.
- Review your practice's own forms.
- What to look for – is counterparty:
 - Enabled to access, exchange and use EHI and achieve the intended actions via the interoperability element?
 - Charged any royalty? If so, the royalty charges must be reasonable and not based on control of the EHI data.
 - Required not-to-compete?
 - Required to exclusively deal?
 - Required to license any IP to exchange for access to interoperability elements?
 - Required to pay a separate fee for access to the interoperability elements (if so, review fee exception)?
 - Required to keep confidentiality (beyond HIPAA) or not to disparage?
 - Allowed to access data post-termination?
- Royalty and non-royalty terms must not discriminate between licensees. For example, competitors cannot be charged at a higher rate.

Penalties and Enforcement

- For providers, ONC has not established (yet) a mechanism for information blocking penalties.
- But remember that providers must agree to "prevention of information blocking" in order to meet CMS promoting interoperability merit-based incentive payment system (MIPS) reporting requirements.
- But remember that penalties may apply if you are a HIE/HIN/developer – up to \$1M.
- But remember that HIPAA penalties may apply for denying access.

Example – Delaying Test Results

“I really don’t want my patients to have access to a bad test result until I can explain it to them...”





Example

“So I have this new mobile app, and I’d like to have all my files uploaded to it...”

Example

“Hi, this is Anderson Neurology. I need Amy Murray’s medical record sent over immediately.”



Example

“We’d be happy to give you broader access to our EHR system, but we need you to sign this Confidentiality Agreement first.”



ELECTRONIC HEALTH RECORD ACCESS USER AND CONFIDENTIALITY AGREEMENT WITH THE DOCTORS CLINIC, PART OF FRANCISCAN MEDICAL GROUP

This Agreement must be completed and signed by each individual requesting access to The Doctors Clinic’s, part of Franciscan Medical Group, Greenway Intergy Electronic Health Records. The Agreement must be completed and returned to representatives of The Doctors Clinic’s Information Technology Department before access will be granted.

Name of Individual Requesting Access (please print): _____

Community Partner Name and Address: _____

I am requesting access to the Greenway Intergy electronic health record system that is used by providers at Franciscan Medical Group’s The Doctors Clinic locations (TDC), part of Franciscan Health System in Tacoma, Washington to obtain Electronic Health Records, and I agree to the following terms and conditions:

Breach means the unauthorized acquisition, access, use, or disclosure of protected health information not permitted by the Privacy and Security Regulations which compromises the security, privacy, or integrity of protected health information.

Community Partner provides health care services to patients in the community of TDC. Community partners may consist of a physician, practitioner, health care provider, group practice, partnership, or corporation of physicians and/or practitioners, health care providers, and its employees.

Thank You!

Russell Anderson

(203) 330-2271

randerson@pullcom.com

Amy Murray

(203) 330-2282

amurray@pullcom.com

Check out Pullman & Comley's

<https://cthealthlawblog.com/>

for more updates!





These slides are intended for educational and informational purposes only. Readers are advised to seek appropriate professional consultation before acting on any matters in this update. These slides may be considered attorney advertising. Prior results do not guarantee a similar outcome.