INVITAE

Role of Health IT in Patient-Directed Data Sharing, and the Potential Impact of the Cures Act Information Blocking Rules

October 2023

Patient Organizations Increasingly Driving and Funding Research

- Patient organizations expanding their roles, including developing patient registries and funding scientific research.

- Nearly 700 deals with an estimated aggregate value of $2.4 billion have been publicly announced between patient organizations and life sciences companies over the past 15 years.

- Following passage of the 21st Century Cures Act (2016), “seismic shift” in how patient organizations collaborate with life sciences companies and facilitate research.

Supporting Patients Through Research Collaboration: Interactions Between Patient Organizations and Life Sciences Companies, IQVIA Institute for Human Research (2023).

21st Century Cures Act (2016)

- “Interoperability” initiatives (Title IV) prioritized sharing of electronic health information:
  - Requirements for certified electronic medical record technology to adopt open, standard (FHIR) APIs to enable access to electronic information by patients and other entities.
  - Prohibitions on “information blocking” (regulations from HHS Office of the National Coodinator for Health IT (ONC))

- Information blocking rules should unlock the sharing of electronic health information in major ways.

- Essentially, the rules establish penalties for interfering with the sharing of electronic health information for any legally permissible purpose.
  - Sharing with patients is a major priority of these initiatives.

Who is Covered?

- Health care providers (defined in Public Health Service Act)

- Certified electronic medical record vendors
    - For all products that facilitate interoperability (not just the certified technology)

- Health Information Exchanges/Networks (functional definition)

What data is covered?

- Electronic health information
    - Protected electronic health information (EHI) that meets the HIPAA definition of “designated record set” (i.e., information that patients have the right to access)
    - Designated record set is all information in the medical record plus information in other records that is used to make decisions about individuals.
    - Not just limited to information in certified electronic medical record systems.

What is “information blocking”?

- Information Blocking: An act *or omission* that “except as *required* by law or specified by the Secretary [in rulemaking], is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information [EHI].” (§4004 of Cures)
- Applies to *any* request for information, for *any* purpose
- Not limited to just information held in certified electronic medical record systems or exchanged via certified capabilities.

Knowledge Standard

Health Care Provider:

“…knows that such practice is ***unreasonable*** and is likely to interfere with the access, exchange or use of electronic health information…”

Health IT Developer of Certified Health IT & HIN/HIE:

“…knows, or should know, that such practice is likely to interfere with the access, exchange or use of electronic health information….”

Timelines

- Rules have been in effect since April 5, 2021.

- HHS ONC guidance (https://www.healthit.gov/faqs)

- Penalties against certified EHR vendors and Health Information Exchanges of up to $1 million per violation – can be levied by HHS OIG (any time after 9/2/2023).

- HHS required to establish disincentives for providers who information block (proposed rule expected from the ONC this fall).

Safe Harbors – actions (or failures to act) that are NOT information blocking

1. Preventing harm exception
2. Privacy exception
3. Security exception
4. Infeasibility exception
5. Health IT performance exception
6. Content and manner exception
7. Fees exception
8. Licensing exception

Impact on Research?

Info blocking "will almost always be implicated" when a practice interferes with access/exchange/use of EHI for these purposes:

- Providing patients with access to their EHI and the ability to exchange and use it without special effort (also charging individuals a fee to electronically access their EHI)
- Ensuring health care professionals, caregivers, and other authorized persons have EHI for treatment and care coordination
- Ensuring payers get information they need to "assess clinical value" and promote transparency of cost and quality of care
- Ensuring providers can get information for quality improvement and population health management activities
- Supporting access/exchange/use for patient safety and public health purposes.

Data Acquisition Process

Collecting longitudinal records on behalf of patients

Stanford Medical Center
300 Pasteur Dr, Stanford, CA 94305

I request the following type(s) of information

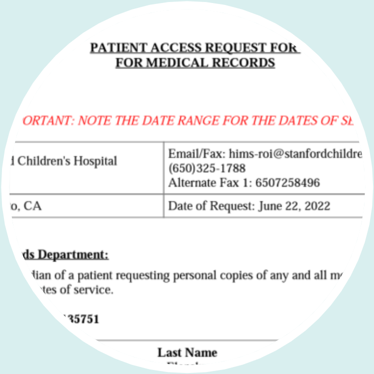
● Medical Records
○ Imaging
○ Both

Will you have future appointments here?

● Yes

Patient identifies providers where they have received care*

*Ciitizen also finds additional providers through a) notes in medical recordsa and b) HIE record locator service,



PATIENT ACCESS REQUEST FOR
FOR MEDICAL RECORDS

ORTANT: NOTE THE DATE RANGE FOR THE DATES OF SE

l Children's Hospital	Email/Fax: hims-roi@stanfordchildre (650)325-1788 Alternate Fax 1: 6507258496
o, CA	Date of Request: June 22, 2022

ds Department:

lian of a patient requesting personal copies of any and all m
tes of service.

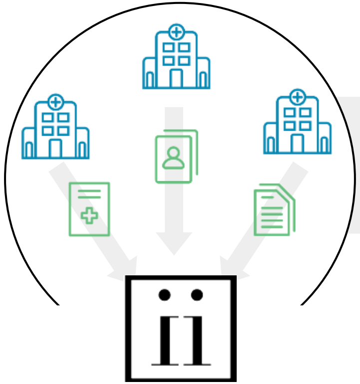
35751

Last Name

Request is generated on behalf of the patient and sent to provider

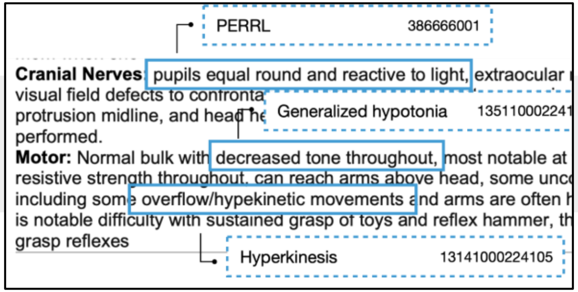
Provider sends back data, which is directly uploaded into the patient's profile

Documents to **data**: patient-consented, research ready.



Platform **follows the patient** and requests medical records from *all* providers patient sees (average 6+ providers)

Medical records and **images** are automatically made available to patients for their own use **across providers**



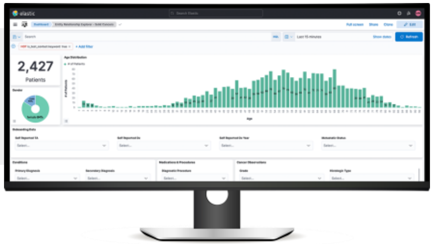
PERRL 386666001

Cranial Nerves: pupils equal round and reactive to light, extraocular
visual field defects to confronta
protrusion midline, and head he
performed.
Motor: Normal bulk with decreased tone throughout, most notable at
resistive strength throughout, can reach arms above head, some unc
including some overflow/hypekinetic movements and arms are often h
is notable difficulty with sustained grasp of toys and reflex hammer, th
grasp reflexes

Generalized hypotonia 135110002241

Hyperkinesis 13141000224105

Raw records processed to **extract, normalize, and codify** defined data elements



With patient consent, regulatory-grade, patient-level data is **structured and shareable** for research

Ciitizen generates **10+ years** of n-of-1 level **regulatory-grade data** across providers and data modalities and enables **prospective data collection** via deep, meaningful **patient relationships**

Information Blocking Rule - Support for Other Research Models?

- Information blocking didn't change research rules - but could change the way entities covered by information blocking rules respond to research requests.

- For example: submission of research request with external IRB approval and waiver/modification of consent (or presentation of proof of consent)
  - Can institution reject in favor of its own IRB determination?
  - Can institution impose high fees?
  - Can institution impose additional terms as part of a data use agreement?
- Could depend on whether "research" becomes an information blocking enforcement priority.

"How the Cures Act Information Blocking Rule Could Impact Research" (Bitterman, McGraw & Mandl, *Forefront* (June 29, 2022) https://www.healthaffairs.org/do/10.1377/forefront.20220623.777837)