



# How to figure out your information blocking exposure

Which penalties and disincentives might apply to you

*June 24, 2020*

# Today's speakers



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# How did we get here?

Bipartisan 21<sup>st</sup> Century Cures Act was signed into law in 2016

## General provisions of the Cures Act



Allocate funds for opioid misuse prevention efforts and biomedical research



Accelerate drug and medical device approval processes



Bolster mental health treatment reform



## Focus on health data



Encourage patients' **electronic access** to their health information



Promote **interoperability** and use IT to improve quality of care



Inhibit **information blocking**

*“Patients needed a game-changer—and it is our hope that history will look back at the Cures effort as the moment in time when the tide finally turned against disease.”*

Joint statement from Rep. Diana DeGette (D-Colo.) and House Energy and Commerce Committee Chair Fred Upton (R-Mich.), the legislation's main sponsors

# What is information blocking?

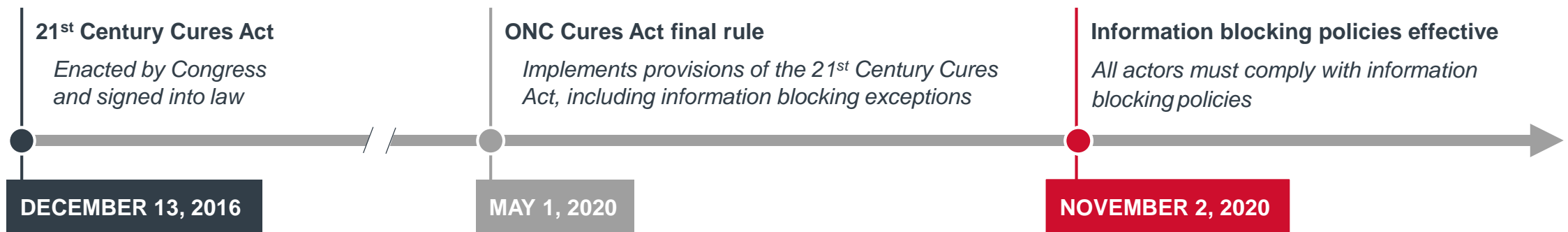
HHS authorized to establish reasonable exceptions through rulemaking

“

A practice that is likely to interfere with, prevent, or materially discourage 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



# Today's focus: information blocking "actors"

## Key components of the ONC Cures Act final rule

TOPIC

POLICIES FINALIZED IN ONC CURES ACT FINAL RULE

<b>1</b> Information blocking	<ul style="list-style-type: none"><li>• Defines who is subject to information blocking policies, called "<b>actors</b>," including providers, IT developers, health information networks (HINs) and health information exchanges (HIEs)</li><li>• Establishes <b>8 exceptions</b> to information blocking</li></ul>
<b>2</b> 2015 Edition CEHRT	<ul style="list-style-type: none"><li>• Requires IT vendors to <b>update 2015 Edition Certified EHR technology</b> (CEHRT) and deploy those changes to providers</li><li>• Formalizes Fast Healthcare Interoperability Resources (FHIR) as API standard</li><li>• United States Core Data for Interoperability (USCDI) expands upon and replaces Common Clinical Data Set (CCDS)</li><li>• Removes, revises certain existing 2015 Edition criteria, adds new criteria</li></ul>
<b>3</b> Maintenance and conditions of certification	<ul style="list-style-type: none"><li>• Updates requirements for IT vendors to remain in good standing under the <b>ONC Health IT Certification program</b></li></ul>

# Three types of information blocking “actors”

Provider organizations could also fall under IT developer or HIE/HIN



## 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.”

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# Why Does It Matter If a Provider Is Also an IT Developer or HIN/HIE?

- Different Categories of Actors are Subject to Different Penalties Under the Law
  - Providers
    - Cures Act requires the U.S. Department of Health and Human Services, Office of Inspector General (OIG) to refer providers to an appropriate agency for “**appropriate disincentives**”
    - ONC sought comment on potential disincentives in its proposed rule, but did not finalize any disincentives
    - *Note that providers separately remain subject to information blocking attestation requirements under the Promoting Interoperability Program*
  - IT Developer and HINs/HIEs
    - OIG may impose **\$1M+ civil monetary penalties** (CMP) per violation
    - OIG proposes to define a violation as each practice that constitutes information blocking, so penalties could add up quickly



# When Might a Provider Also Be an IT Developer or HIN/HIE?

- **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 [IT] . . . 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 the . . . ONC Health IT Certification Program”



# When Might a Provider Also Be an IT Developer Or HIN/HIE? (cont.)

- **HIN/HIE**

- “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 electronic health information:
  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** purposes, as such terms are defined in [the HIPAA Privacy Rule]”
- Under the final rule definition, parties that act as **intermediaries in essentially bilateral exchanges**—for example, an intermediary that receives EHI from one party in a non-standardized format and converts it to standardized data for the receiving party—**would not be an HIN or HIE** for information blocking purposes

# HIN/HIE Hypothetical



**Scenario 1:** A large provider establishes a network to facilitate the movement of EHI among a group of smaller providers and itself, creating a new entity to administer the network's policies and technology

**Scenario 2:** A provider that is also an HIN/HIE denies an individual's access to EHI via the provider's patient portal



# Key Questions for Health Systems That Offer Certified Health IT

1. Does the health system host (in its data center or through a third-party) the EHI created by or received on behalf of the community providers?
2. Does the health system exercise control over some or all of the EHI created or received by community providers in the certified health IT?
  - For example, does the health system control the EHR system configuration settings that determine whether a particular user has access to EHI in the EHR system?

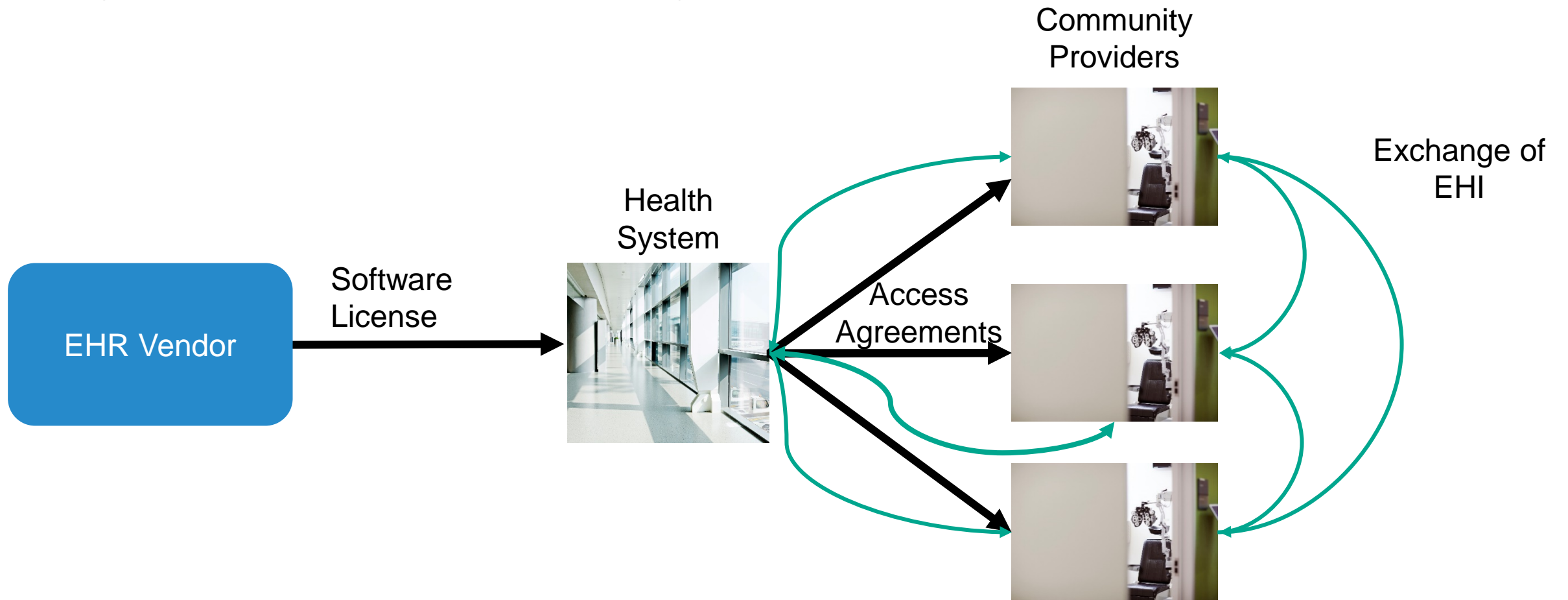


# Additional Key Questions for Health Systems That Are IT Developers *or* HINs/HIEs

1. Does the health system condition access to the EHR system (including, for example, its HIN/HIE functionality) on the community provider's provision of intellectual property rights?
2. Does the health system's EHR access agreement with a community provider address the disposition of records maintained within the EHR upon termination of the agreement?
3. Does the health system control the timing and implementation of bug fixes, upgrades and other software maintenance to the EHR system (including its HIN/HIE functionality)?

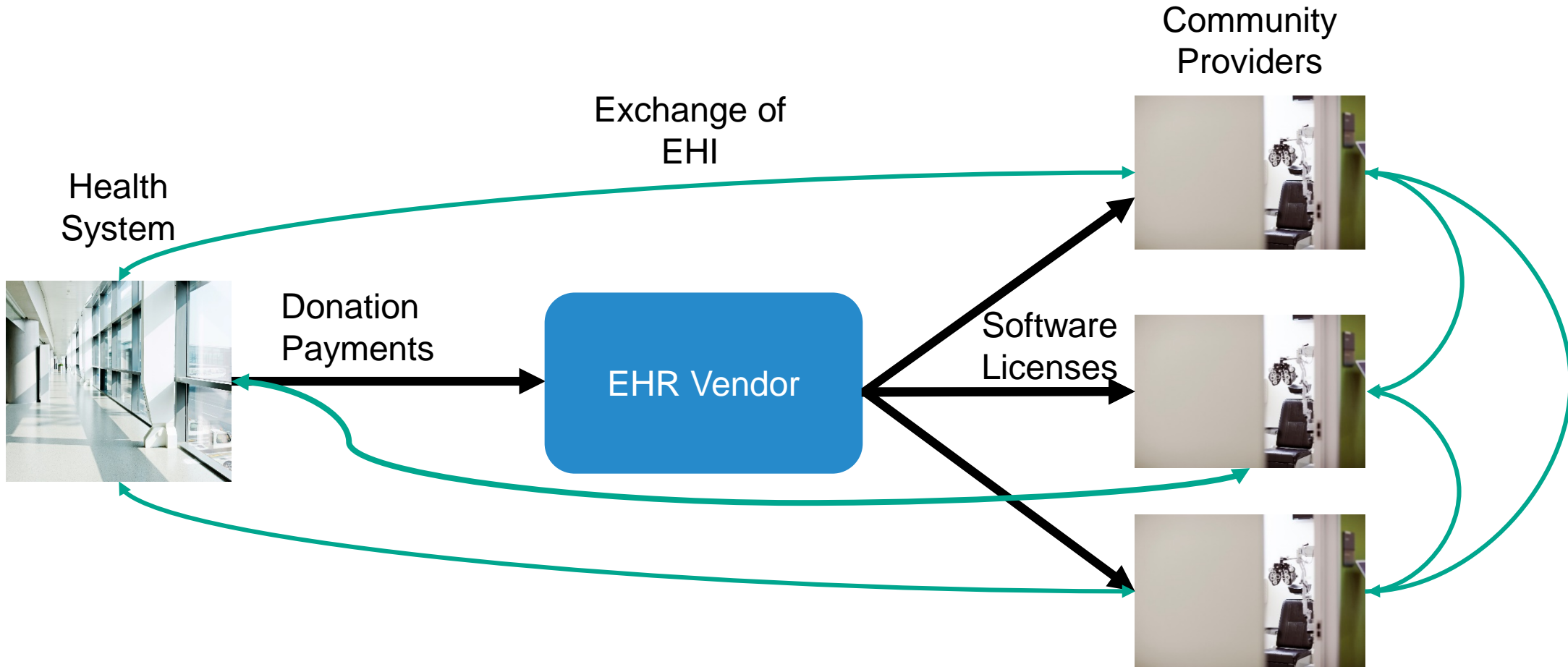


# Hypothetical – Health System as HIN





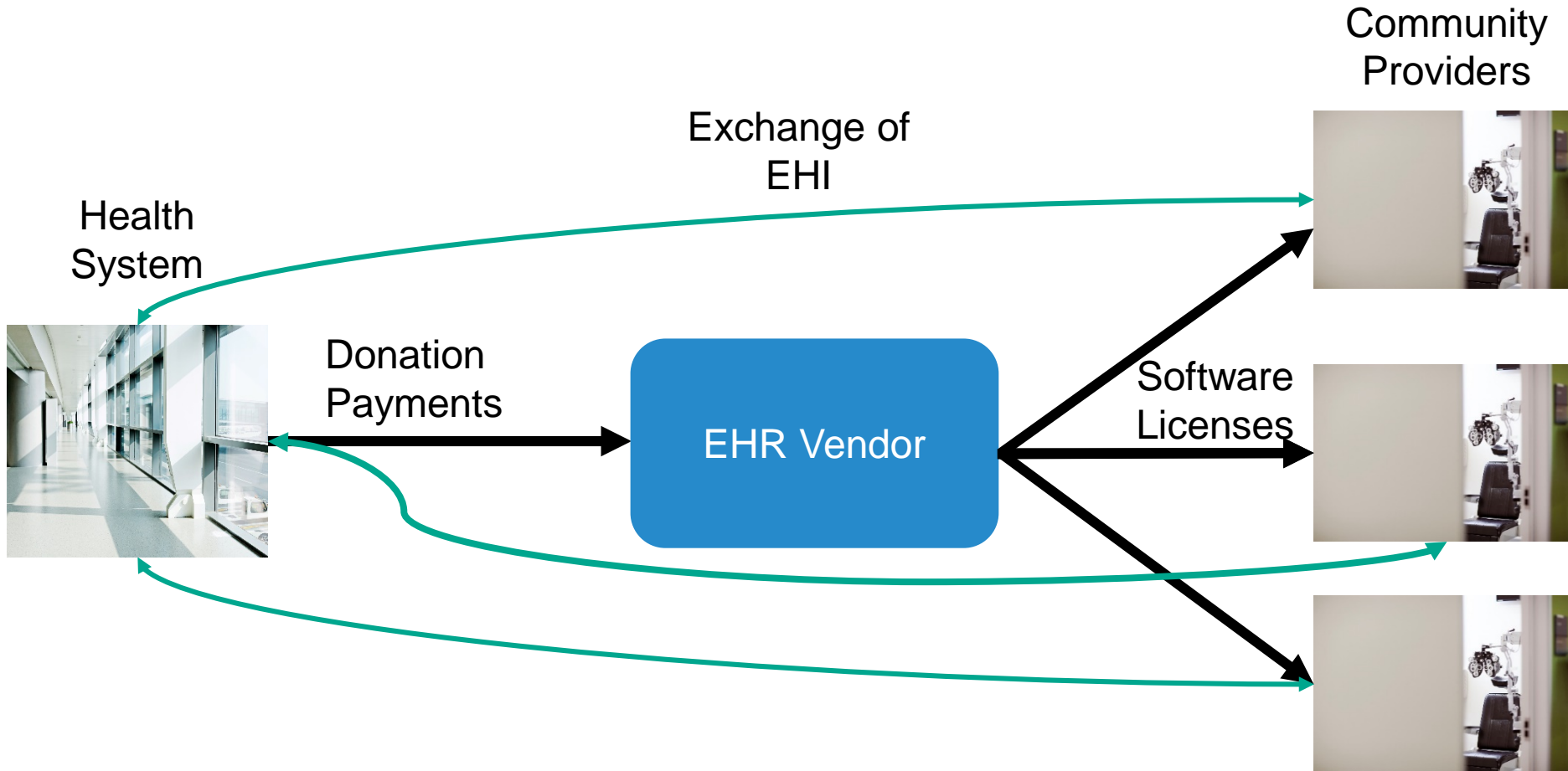
# Hypothetical – EHR Donation





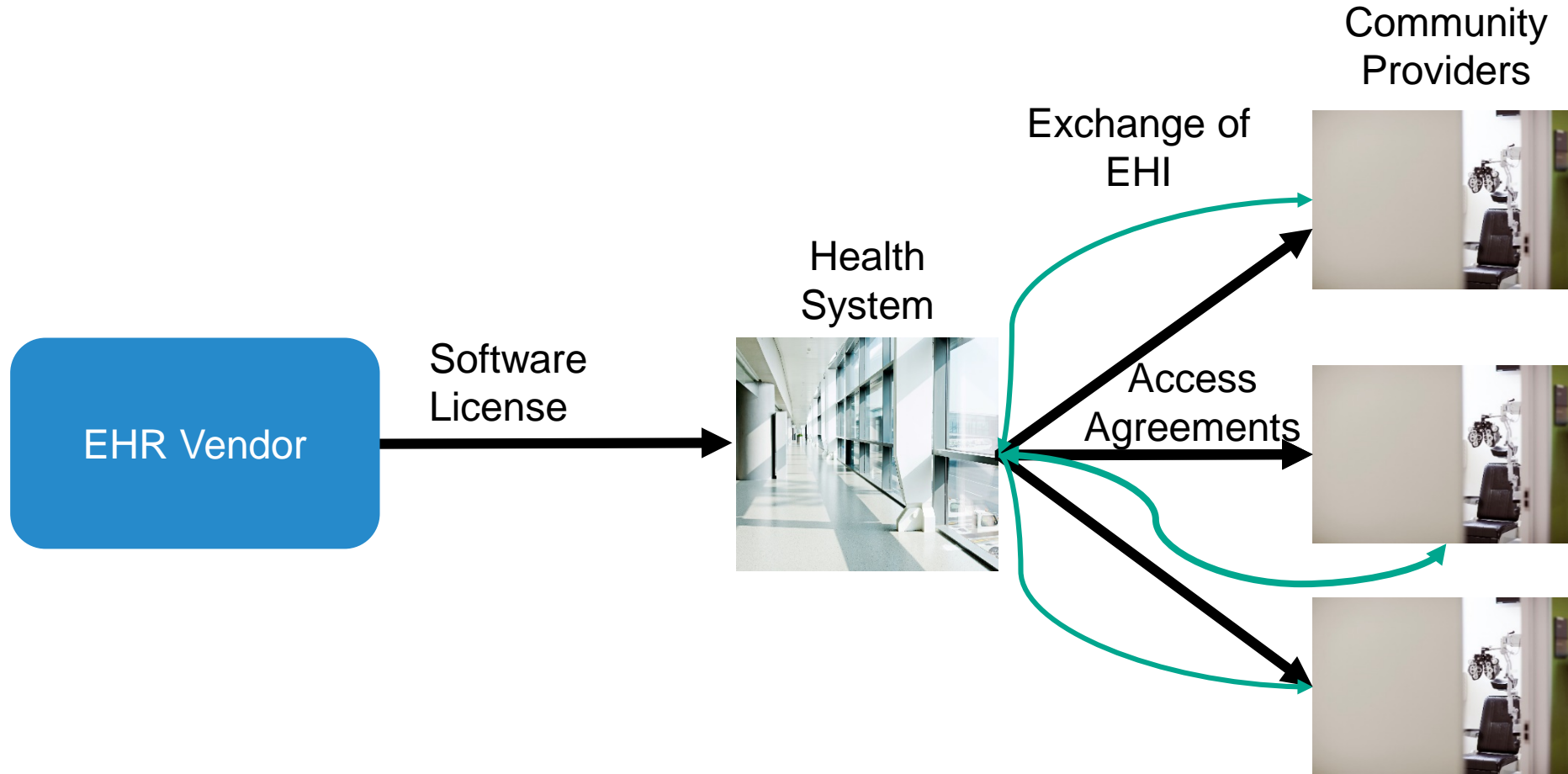


# Hypothetical – Bilateral Exchange





# Hypothetical – Bilateral Exchange





# Information Blocking Investigations and Enforcement

- **OIG investigative authorities**
  - Pre-Cures Act, OIG’s authority to pursue information blocking was limited
  - The Cures Act granted OIG to investigate:
    - claims of information blocking, and
    - alleged false attestations by IT developers
  - According to ONC, the **actor bears the burden** of demonstrating that a practice meets an exception if ONC or OIG pursues an information blocking claim
- **Timing**
  - Actors have until **November 2, 2020** to comply with the information blocking provisions
  - **No CMP enforcement** by OIG until after OIG finishes its notice and comment rulemaking



# OIG Proposed Rule

- April 24, 2020:
  - OIG published in the *Federal Register* a **proposed rule** to, among other things, incorporate its new CMP authorities for information blocking into OIG’s existing CMP regulations
  - OIG intends for the proposed information blocking enforcement regulations to “improve coordination within the health care system and patients’ access to their health care data”
- OIG **will not** impose CMPs before ONC’s information blocking compliance date (November 2, 2020)
- OIG proposes to **begin imposing** at least 60 days after it issues a final rule (but is considering alternative specific dates)



# Complaint Process and Agency Coordination

- Complaint process
  - ONC developed a **dedicated information blocking complaint process**
    - Complaints submitted to ONC receive certain **protections from public disclosure** under the law
    - ONC's process also allows for the **anonymous submission** of complaints
  - OIG also has processes to receive and review information blocking claims
- Agency coordination and preparation
  - ONC is **actively coordinating with OIG** to establish processes for **sharing complaint information** between the agencies
  - OIG plans to:
    - Train its investigators to spot information blocking allegations **as part of its other fraud and abuse investigations** and
    - Implement information blocking complaint review and triage procedures



# Enforcement Risks for Covered Actors

- Potential sources of information blocking allegations include:
  - The Federal Government (watch for a “normal” OIG investigation + information blocking allegations)
  - Competitors
  - Parties to existing arrangements
  - Patients and Patient Advocacy Groups
- OIG enforcement focus:
  - Conduct that (1) involves **patient harm**; (2) **impacts** providers’ **ability to deliver patient care**; (3) **continues** for a long time; (4) **results in financial loss** for Medicare, Medicaid, and other federal health care programs as well as other government and private entities; and (5) involves an actor engaging in the conduct with **“actual knowledge”**



# Your Panel



## **JAMES A. CANNATTI III**

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### **CAPABILITIES**

James practices at the intersection of today's most pertinent health care issues, including digital health, health IT policy, and fraud and abuse, including Anti-Kickback Statute/Stark Law matters. With more than 10 years of experience in the US Department of Health and Human Services' Office of Inspector General most recently as Senior Counselor for Health Information Technology, James is well-attuned to the regulatory issues impacting the rapidly evolving digital health landscape, including information blocking and interoperability; electronic health records; and value-based care.



# Your Panel



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Scott A. Weinstein provides legal counsel on health care regulatory compliance, contracting and transactional due diligence, with a focus on health information privacy and security, health information technology certification requirements, and clinical research regulations. Scott additionally provides legal counsel on federal and state privacy and data protection laws, including assistance with privacy audits and the development of internal and externally facing privacy policies for websites and mobile applications. Previously, Scott served as a presidential management fellow in the US Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC).



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# For more on the ONC final rule and information blocking

Check out these related resources

## ▶ Advisory Board



[“How to prioritize your response to the ONC Cures Act final rule: A guide for providers on the compliance timeline for information blocking and CEHRT updates”](#)



[“Ready-to-use Slides: Prevention of Information Blocking Overview and Guidance”](#)

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[“Could Offering EHR System Access to Community Providers Lead to Civil Monetary Penalties for Information Blocking?”](#)



[“Special Report: ONC Releases Final Rule Implementing Cures Act Information Blocking Prohibition”](#)

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1. MU = Meaningful Use.
2. PI = Promoting Interoperability.
3. IQR = Hospital Inpatient Quality Reporting Program.

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