



# Just What the Doctor Ordered!

How you can use the Information Blocking Rule as a prescription for getting information from providers

**Tom Bixby**

Principal  
Thomas D. Bixby Law Office LLC

© 2022 Blue Cross Blue Shield Association. All Rights reserved. The 2022 BCBS National Summit is a program of the Blue Cross Blue Shield Association, an association of independent Blue Cross and Blue Shield companies. All company names, logos, and brands contained in the presentation are property of their respective owners, used for identification purposes only, and are in no way associated or affiliated with the Blue Cross and Blue Shield Association. Use of these names, logos, and brands does not imply endorsement.

1

# Agenda

- Requesting (and Getting) PHI for Blue Plans
- The Information Blocking Rule:
  - What information is subject to Rule?
  - Who is Covered?
  - What is Information Blocking?
- Exceptions to the Information Blocking Rule
- Information Blocking Rule: Enforcement
- HIEs/HINs and the Information Blocking Rule



2

# Requesting (and Getting) PHI for Blue Plans

3

## Blue Plan Requests for PHI

### Purpose of Request

- ✓ Star Ratings/HEDIS
- ✓ Value-Based Payment Arrangements
- ✓ Case Management/Care Coordination

### HIPAA Purpose

- ✓ Health care operation
- ✓ Payment activity
- ✓ Health care operation

4

4

## Applicable HIPAA Provisions

- **Provider may disclose PHI for Blue Plan's HCO:**
  - Each party has or had relationship with individual
  - PHI pertains to the relationship and
  - Disclosure is for specified health care operations
  - *45 C.F.R. § 164.506(c)(4)*
- **Specified health care operations**
  - Quality assessment & improvement activities
  - Case management care coordination
  - Population-based activities related to improving health/reducing costs
  - Evaluating practitioner/provider performance
  - Health care fraud & abuse detection and compliance

## Applicable HIPAA Provisions

- **Provider may disclose PHI for Blue Plan's Payment:**
  - No additional requirements for disclosure
  - *45 C.F.R. § 164.506(c)(3)*
- **Once disclosed, no restrictions**
  - Recipient may use for *any permissible purpose*
  - Contrast with:
    - Business associates
    - Plan sponsors of group health plans
    - Discovery requests (Qualified Protective Orders)
    - Recipient of Limited Data Sets
    - Disclosures for research

## Provider limitations on use & disclosure

- **Limitations on re-use or re-disclosure:**
  - “Use or disclose PHI solely for purposes” for which PHI was disclosed
  - Not use or disclose once patient ceases to be a member
  - Quality metrics only if methodology agreed to by provider
  - Prohibition on using data for claim adjustments
- **Ownership/Licensing/; report breaches**
  - PHI “shall remain property of Hospital”
  - License use of PHI
- **Report breaches/security incidents involving PHI**
- **Return or destroy PHI upon termination of Agreement**

7

## The Information Blocking Rule

8

## Information Blocking

- **21<sup>st</sup> Century Cures Act (2016)**
  - Prohibited “Information Blocking”
  - Defined practices that qualified
    - “Practices that *restrict authorized access, exchange, or use* for permitted purposes”
  - Directed HHS to draft rules
    - Office of the National Coordinator for Health Information Technology (**ONC**)
- **PHSA § 3022 (42 U.S.C. § 300jj-52)**
  - Not effective before HHS identifies exceptions
    - “Reasonable and necessary activities that do not constitute information blocking”

## Information Blocking Rule

- **ONC published May 1, 2020**
  - Applies to Electronic Health Information
    - Initially limited to data elements in USCDI standard
  - “Actors” subject to Rule are:
    - Health care providers
    - Health Information Exchange (**HIE**) or Health Information Network (**HIN**)
    - Health Information Technology Developer
- **Compliance date**
  - Original date November 20, 2020
  - Later postponed to April 6, 2021
    - Applies to *all* Electronic Health Information beginning October 6, 2022

# Information Blocking Rule

- **45 C.F.R. Part 171**
- **Electronic Health Information**
  - Electronic *Protected Health Information* (as defined in HIPAA)
  - Limited to information in Designated Record Set (all PHI in EHR)
  - Until October 6, 2022, limited to USCDI data elements
- **USCDI data elements**
  - United States Core Data for Interoperability
  - Set of data classes and constituent data elements
  - Standard for Providers' Electronic Health Records

11

<p><b>Allergies and Intolerances *NEW</b></p> <ul style="list-style-type: none"> <li>• Substance (Medication)</li> <li>• Substance (Drug Class) *NEW</li> <li>• Reaction *NEW</li> </ul>	<p><b>Clinical Notes *NEW</b></p> <ul 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> </ul>	<p><b>Patient Demographics</b></p> <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>	<p><b>Smoking Status</b></p>
<p><b>Assessment and Plan of Treatment</b></p>	<p><b>Goals</b></p>	<p><b>Problems</b></p>	<p><b>Unique Device Identifier(s) for a Patient's Implantable Device(s)</b></p>
<p><b>Care Team Members</b></p>	<p><b>Health Concerns</b></p>	<p><b>Procedures</b></p>	<p><b>Vital Signs</b></p> <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 old) *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>	<p><b>Immunizations</b></p>	<p><b>Provenance *NEW</b></p> <ul style="list-style-type: none"> <li>• Author Time Stamp</li> <li>• Author Organization</li> </ul>	
	<p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>• Tests</li> <li>• Values/Results</li> </ul>		
	<p><b>Medications</b></p>		

12

## Actors subject to the Rule

- **Health Care Providers**

- Hospitals, SNFs, home health, long term care
- Health care clinic, FQHC, group practice, physicians, practitioners
- Pharmacies, laboratories
- “Any other category of health care facility, entity, practitioner, or clinician” deemed appropriate by ONC

- **Health Information Technology Developer**

- Entity that develops or offers Health Information Technology
- That has (at least) one health module certified by ONC

## “Actors” subject to the Rule

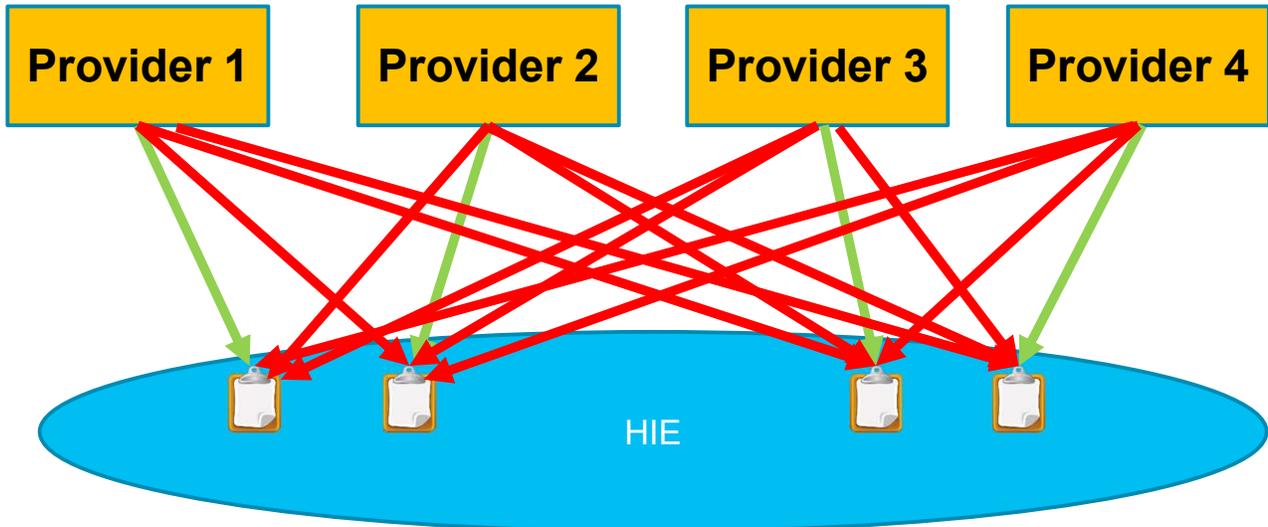
- **Health Information Exchange/Network**

- HIEs = HINs
- Entity that permits or enables access, exchange, or use of EHI—
  - Among two or more other unaffiliated entities
  - That are enabled to exchange EHI with one another
  - For treatment, payment, health care operations

- **Unaffiliated Entities’ exchange of EHI**

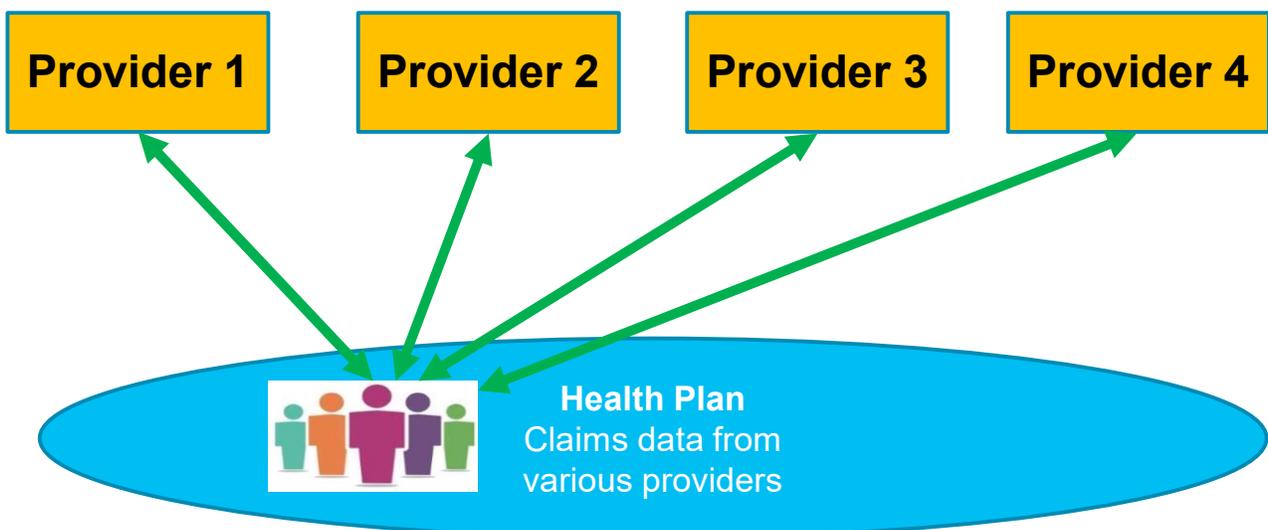
- Not applicable to “bilateral exchanges” of EHI
- Unaffiliated entities must have ability and discretion to exchange PHI with each other

## Multilateral Exchange of EHI is a HIE/HIN Function



15

## Bilateral Exchange of EHI does not make a Health Plan an HIE/HIN



16

## What is Information Blocking?

- **Practice that is:**
- **(a) Likely to “interfere with”**
  - Prevent, materially discourage, or otherwise inhibit
- **(b) Permissible access, exchange or use of PHI *and***
- **(c) Actor knows practice is likely to:**
  - Interfere with, prevent, or materially discourage
  - Access, exchange, or use of ePHI
    - HIE/HIN—knows or *should know* Practice is likely to interfere with access . . .
    - Provider must also know the Practice is *unreasonable*

17

## What is Information Blocking?

- **Information Blocking does *not* include a Practice:**
  - Required by law or
  - Covered by an exception
- **Prohibited practice includes acts and omissions**
  - Refusal to exchange EHI
  - Failure to timely respond to request
- **In short, Information Blocking is—**
  - “A practice that unreasonably limits the availability and use of EHI for authorized and permitted purposes”

18

## Prohibition on Information Blocking

“if an actor is **permitted** to provide access, exchange, or use of EHI under the HIPAA Privacy Rule, then the information blocking provision would **require** that the actor provide that access, exchange, or use of EHI so long as the actor is not prohibited by law from doing so [and no exception applies].”

## Information Blocking Examples

### • Specific examples:

- Formal restrictions on access exchange or use
  - Expressed in contract or license terms (e.g., prohibition on redisclosure)
  - Internal policies and procedures (e.g., requiring consent for disclosure)
- Exercise of intellectual property rights that restrict access, exchange, or use
- Actor “simply refuses to exchange or facilitate access” to EHI
- Incorrectly claiming HIPAA (or other law) prevents disclosure
- Imposing discriminating fee schedules for interfaces

### • Practices that “almost always implicate” Rule:

- Individual access to their records
- Provider access for treatment
- Payers’ access necessary to “effectively assess . . . quality and costs of HC”

# Information Blocking

- **Subjective factors in definition of term—**

- Actor must know (or should know);
- Practice that is *likely to interfere with* access, exchange, or use
- Practice that is *unreasonable*
- Others in Exceptions
  - Tailored to meet exception
  - No improper encouragement or inducement

- **Evaluation of Information Blocking Practice:**

“requires a fact-based, case-by-case assessment of the circumstances”

## Exceptions to the Information Blocking Rule

## Exceptions to Information Blocking

- **Practice not Information Blocking if Exception applies**
  - Actor must satisfy:
    - All applicable conditions of an exception
    - At all relevant times
- **Two categories of Exceptions**
  - Not fulfilling requests for access, exchange, or use of EHI (5)
  - Procedures for fulfilling requests (3)

## Exceptions to Information Blocking

- **Exceptions—not fulfilling requests**
  - Preventing harm exception
  - Privacy exception
  - Security exception
  - Infeasibility exception
  - Health IT performance
- **Procedural Exceptions**
  - Content and manner exception
  - Fees exception
  - Licensing exception

# Privacy Exception

- **Four “Sub-Exceptions”**

- Precondition not satisfied
- Individual’s request not to share PHI
  
- Health IT Developer of Certified Health IT—not subject to HIPAA
- Denial of Individual’s request for own PHI

# Privacy Exception

- **Sub-Exception: Precondition not satisfied**

- Practice (of denying request) must be tailored to precondition
- Implemented consistently, without discrimination
- Written policies & procedures, explicit criteria training
- Case-by-case documentation of practice application

- **Sub-Exception: Individual’s request not to share**

- Actor may elect to honor individual request to withhold EHI
- Based on Individual’s request
- Without improper encouragement, inducement, or request
- Applied in consistent and non-discriminatory manner
- Actor documents request within reasonable time

## Exceptions to Information Blocking

- **Procedural Exception: Fees**

- Must be based on objective & verifiable criteria
- Uniformly applied for all similarly situated classes
- Reasonably related to Actor's costs of providing access
- Reasonably allocated among all similarly situated classes

- **Procedural Exception: Licensing**

- Actor may license access to “Interoperability element”
- Must begin negotiations within 10 days; close within 30
- Reasonable royalty for use of technology
- NDA—limited to Actor's trade secrets identified “with particularity” in NDA
- NDA applies to trade secrets—not EHI

## Information Blocking Rule: Enforcement

## Enforcement of Rule

- **Penalties vary, depending Actor type**

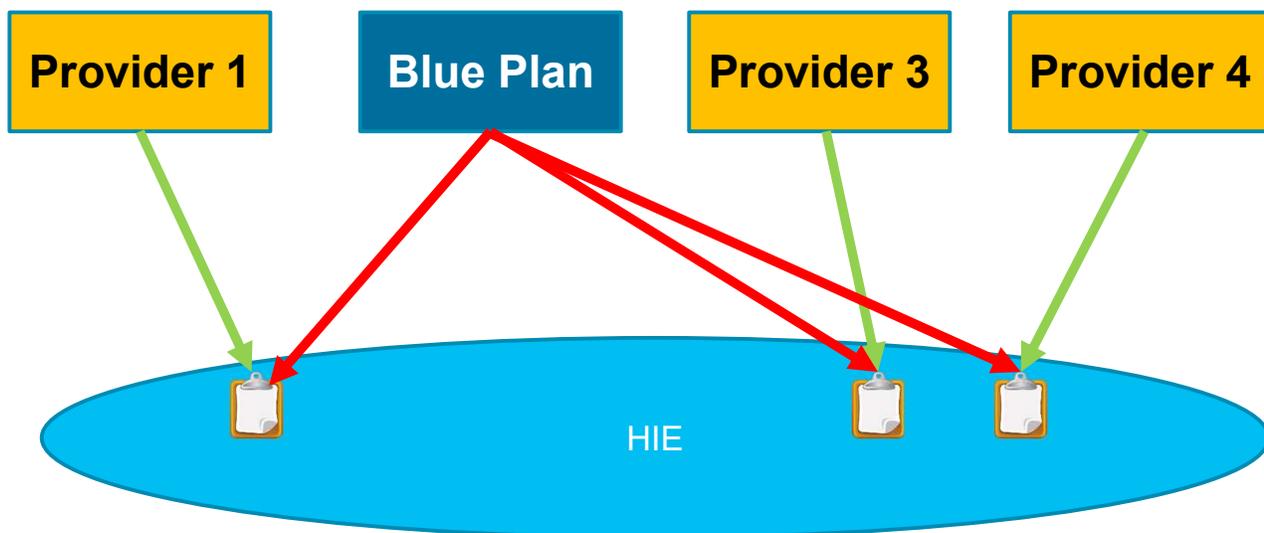
- HIEs/HINs: up to \$1,000,000/ violation
- Health IT Developer of Certified Health IT: up to \$1,000,000/ violation
- Health care provider: “appropriate disincentives” per HHS Rules

- **Reporting Information Blocking**

- ONC Portal <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6>
- ONC investigates matters related to Health IT Certification
- Office of Inspector General investigates all types of Blocking claims
- Will have authority to impose sanctions

## HIEs/HINs and the Information Blocking Rule

## Blue Plans can participate in HIEs/HINs too!



31

## Blue Plans: Information from HIEs/HINs

- **HIEs/HINs collect EHRs from numerous providers**
  - Single connection likely to be more efficient
  - Compliance threshold lower than for providers
  - Penalties for failure to comply higher than providers

32

# Questions?

Tom Bixby

[tbixby@tbixbylaw.com](mailto:tbixby@tbixbylaw.com)  
(608) 661-4310

 BlueCross.  
BlueShield. | 2022 NATIONAL  
SUMMIT

33

# Thank You

 BlueCross.  
BlueShield. | 2022 NATIONAL  
SUMMIT

© 2022 Blue Cross Blue Shield Association. All Rights reserved. The 2022 BCBS National Summit is a program of the Blue Cross Blue Shield Association, an association of independent Blue Cross and Blue Shield companies.

34