

Privacy Laws Governing Uses & Disclosures of Data for PCOR

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Federal Laws that Permit Use & Disclosure for Research

HIPAA

Part 2

FERPA

The Privacy Act

HIPAA - Permissions

- Covers only covered entities & their business associates (not all health data)
- Governs identifiable data (protected health information or PHI)
- Permits uses and disclosures of PHI for TPO+ (no consent requirement)
- Permits uses and disclosures of PHI for research
 - Authorization required but can be waived by Privacy Board or IRB
 - Can obtain broad consent for future research uses
 - Can use limited data set
- **De-identified data (safe harbor or expert method) not covered by HIPAA.**

State Laws

- Stronger state laws not preempted by HIPAA
- Typically govern access to data on minors/adolescents, particularly for sensitive conditions
- Coverage varies – but **like HIPAA, typically cover only identifiable data**

What's New? Information Blocking Rules

Went into effect April 5, 2021

Creates presumption for sharing electronic health information for any lawful purpose (including PCOR)

Applies to health care providers, certified EHR vendors, and health information exchanges

Penalties for “blocking” – up to \$1M per incident for EHR vendors & HIEs; providers referred to CMS for “appropriate disincentives”

8 safe harbor exceptions (ex. privacy, security, harm, infeasibility)

Allergies and Intolerances ***NEW**



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

Assessment and Plan of Treatment



Care Team Members



Clinical Notes ***NEW**

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



Goals



Health Concerns



Immunizations



Laboratory

- Tests
- Values/Results



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 ***NEW**
- Previous Address ***NEW**
- Phone Number ***NEW**
- Phone Number Type ***NEW**
- Email Address ***NEW**

Problems



Procedures



Provenance ***NEW**



- Author Time Stamp
- Author Organization

Smoking Status



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) ***NEW**
- Weight-for-length Percentile (Birth - 36 Months) ***NEW**
- Occipital-frontal Head Circumference Percentile (Birth - 36 Months) ***NEW**



For more info:
HealthIT.gov/USCDI

Power to the Patients

- HIPAA right of access being more robustly enforced
- Information blocking rules prioritize access by patients or apps acting on their behalf
 - More timely access to EHI
- HITECH provisions giving patients the right to direct PHI coming from an electronic health record to a “third party” (such as a researcher) – pending HIPAA rules to implement.