New 42 CFR Part 2 Regulations and Information Sharing

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Agenda

OCHIN Background information
Environment of Data Sharing
Data Sharing and Safeguards
Proposed Rule for 42 CFR Part 2
OCHIN’s Position
Who Is OCHIN?

- OCHIN is a nonprofit health care innovation center designed to *promote access to quality, affordable health care for all.*
- One of the nation’s largest and most successful Health Information Networks

✓ In 18 states, coast to coast
✓ Touching over 4,500 physicians

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OCHIN’s History is One of Innovation

- **2000** OCHIN Founded
- **2002** OCHIN began providing Epic Practice Management to Community Health Organizations
- **2005** OCHIN makes Epic EHR available to Community Health Organizations
- **2007** OCHIN’s Practice-Based Research Network (PBRN) is created
- **2011** Epic Accreditation and OCHIN selected as Oregon’s Regional Extension Center
- **2011** Among the 1st in the country to establish integration with the SSA
- **2011** OCHIN branches out with multiple EHRs with the addition of eCW
- **2012** OCHIN Epic deployed to Corrections, Behavioral, Naturopathic
- **2013** OCHIN is awarded the first PCORI research grant to Oregon
- **2014** OCHIN awarded ADVANCE Clinical Data Research Network & built nation’s most comprehensive clinical datasets on safety net patients
- **2014** Veterans Affairs (VA) bidirectional exchange live
- **2015** OCHIN awarded CHIT0 Partnership and development of Provider Directory and Metric Alignment initiative
- **2016** OCHIN Research publishes Conceptual Model for Social Determinants of Health in Primary Care
- **2016** Managed $25M Investment in Medical Grade Network Infrastructure

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OCHIN States
OCHIN’s Offering is Focused on Health Care Transformation

Technology
Best-of-breed technologies targeted to create population health and support care transformation

Research
Focused on improving the health of underserved populations, enhancing quality of care, and informing health policy

Services
Professional services range from staff augmentation to operational support to strategic planning

Outcome

Data-Only Studies and Analytics
Translational Research
Observational and Natural Experiment Studies

Technology
Aere ODL
Hosted Epic
Connectivity and Telehealth Solutions

Research
Quality Improvement and Leadership Institute
Billing and Financial Consulting
Compliance and Risk Assessment

Outcome

Services
Billing and Financial Consulting
Compliance and Risk Assessment

Environment of Data Sharing
OCHIN exchanged over 8.4 million records with more than 250 organizations in FY2015

- Through Epic Care Everywhere, we exchange with organizations spanning 48 states.
- Through eHealth Exchange, we exchange records with the Social Security Administration, VLER (Virtual Lifetime Electronic Record), and Veterans Health Information Exchange (VHIE).
- Through eHealth Exchange or HL7 interfaces, we connect with Statewide and Regional HIEs.
- Through XDR Direct, we connect with Behavioral Health EHR (Netsmart)

National Engagement on Data Exchange

- OCHIN is an eHealth Exchange Anchor Participant
- OCHIN is a member of the Care Connectivity Consortium (CCC) with
  - Geisinger Health System (PA),
  - Group Health Cooperative (WA)
  - Intermountain Healthcare (UT)
  - Kaiser Permanente (CA)
  - Mayo Clinic (MN)
EHR Adoption Rates between 2008 - 2014

State adoption rates have increased from 2008 to 2014.

Figure 2: State percent of non-federal acute care hospitals with adoption of at least a Basic EHR system compared with prior years.

2008  2011  2014

NR  0-19%  20-39%  40-59%  60-79%  80-100%

NOTES: Basic EHR adoption requires the EHR system to have at least a basic set of EHR functions, including clinician notes, as defined in Table A1. Estimates for states shaded grey did not meet the standards for reliability (NR). See the Table A2 for a complete list of 2009 and 2011 hospital adoption by state.

SOURCE: CHOP, AHA Annual Survey Information Technology Supplement

Data Sharing Strategies and Safeguards
OCHIN Strategies to Support Data Sharing

1. Contractual
2. Technology
3. Operational

Contractual – Organized Health Care Arrangement

• OCHIN and its OCHIN Epic© Members are part of an Organized Health Care Arrangement (OHCA)
• Members of the OCHIN OHCA may disclose PHI To another Member of the OHCA for health care operations activities of the OCHA.
Contractual Agreements

• **Business Associate Agreements** - (BAAs) OCHIN has (BAAs) with each of our Member organizations which describe the permitted and required uses of PHI
  – Data aggregation
  – Limited data sets

• **Member Contracts** – OCHIN has contracts with each of our Member organizations specifying the Epic Care Everywhere Rules of the Road for accessing other non-OCHIN Epic© organization’s patient records

• **Consent Forms** - All OCHIN Members with a Part 2 Program are required to have a Part 2 compliant patient authorization/consent included in the patient’s records in order for those records to be maintained within the Epic© EHR.

Technology – Single OCHIN EPIC Medical Record

• In OCHIN Epic©, a patient has a single medical record, regardless where they are seen within the OHCA

• “Break the Glass” by OCHIN Members is required
  – Requires the user to select a reason for accessing the patient’s record
Technology – Acuere Data Aggregation Tool

- Acuere is a tool that allows Acuere customers (OCHIN and non-OCHIN) to benchmark patient care practices within their own organizations against the aggregate practice standards of other Acuere participants for quality improvement and population health management purposes
  - Proposed rule allows population health management under a QSOA

Operational- Compliance Tools for OCHIN Members

- OCHIN 42 CFR Part 2 Decision Tree tool
- White paper “Patient Privacy in OCHIN Epic© A Guide”
Part 2 Program Patient Authorization/Consent

- If an OCHIN Member has a Part 2 program, and they want their patients’ medical records included within the OCHIN Epic© EHR, OCHIN requires that their patients sign a Part 2 compliant authorization permitting the disclosure to the OCHIN Collaborative.*

* BREAKING NEWS – This aligns with new proposed 42 CFR Part 2 Rule
Patient Privacy in OCHIN Epic© a Guide

• Internal Safeguards
  – Sensitive Encounter Functionality
  – Sensitive Department Functionality

• External Safeguards
  – Care Everywhere Restricted Departments

Patient Privacy in OCHIN Epic© a Guide (Continued)

• Designating a Sensitive Encounter or Department

1. Clinician Treats Patient
2. Clinician determines encounter is sensitive
3. Clinician marks encounter as sensitive
Patient Privacy in OCHIN Epic© a Guide (Continued)

• Break the Glass Process

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Patient Privacy in OCHIN Epic© a Guide (Continued)

• Care Everywhere
  – Restricted Department & Confidential Department
  – Patient Opt-Out
Patient Privacy in OCHIN Epic© a Guide (Continued)

- User security
- Access Reports
- Break the Glass Reports

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Proposed Rule for 42 CFR Part 2
New Proposed Rule 42 CFR Part 2

- February 9, 2016 HHS published proposed 42 CFR Part 2 rule changes
- Comment Period ended April 11, 2016
- Goes into effect 180 days after the final rule is published
- Intended to modernize the rules to facilitate electronic exchanges of substance use disorder (SUD) information
  - Clarifies definitions and consent for release of information requirements

Proposed Changes to 42 CFR Part 2

- Methadone programs (pg 6993)(New §2.4)(Old §2.15(b))
  - Current: must report violations of 42 CFR Part 2 to the FDA
  - Proposed: must report violations of 42 CFR Part 2 to U.S. Attorney’s Office and SAMHSA

- Definition of Patient (pg 6995)(§2.11)
  - Proposed: Patient includes any individual who, after arrest on a criminal charge is identified as an individual with a substance use disorder in order to determine that individual’s eligibility to participate in Part 2 programs. This definition includes both current and former patients.
QSO Definition

- Definition of Qualified Service Organization (QSO) Change
  - **Proposed**: Revise the definition of QSO to include population health management in the list of examples of services a QSO may provide.

- Health Information Exchange (HIE)—SAMHSA uses “entity without a treating provider relationship that serves as an intermediary”

Amount and Kind

- The new rule proposes to require the consent form to explicitly describe the SUD-related information to be disclosed. The types of information that may be requested include: diagnostic information, medications and dosages, lab tests, allergies, substance use history, summaries, trauma history summary, employment information, living situation and social supports, and claims/encounter data.

- Authorization language:
  - **Acceptable**: “All of my substance use disorder related claims/encounter data”
  - **Unacceptable**: “All of my records”
HIEs and Consent

- **Current Approach**: The consent form requires the name of the individual and organization to which a disclosure is made.

- **Proposed Approach**: the new 42 CFR Part 2 regulation is proposing to permit the inclusion of a general designation in the “To Whom” section of the consent form – Examples include:
  - “To OCHIN and all my treating providers”
  - “To all my treating providers at OHSU”

- HIEs and covered entities must have a mechanism in place to determine whether a treating provider relationship exists between the patient and the provider

List of Disclosures and Acknowledgement

- **List of Disclosures**: The HIE and a covered entity must provide a list upon written request (includes for treatment purposes)

- **Written Consent and Acknowledgement**: Patient understands the terms of the consent, and the right for an accounting of disclosures
Confidentiality Restrictions and Safeguards Continued

• Consent Form Revisions
  
  – **Proposed:** Responses sent to the patient electronically may be sent by encrypted transmission or by unencrypted email at the request of the patient as long as the patient has been informed of the potential risks associated with unsecured transmission.

Summary of the Proposed Law - 42 CFR Part 2

• Summary of the Law:
  
  – The notice can be either on paper or in an electronic format
  
  – The notice must contain the contact information for reporting violations
Prohibition on Re-Disclosure Clarifications

• The new rule proposes to clarify the current prohibition on re-disclosure
  – **Prohibited Disclosures**: Conditions
  – **Permitted Disclosure**: Release of medical information unrelated to Part 2 treatment

Medical Emergencies

• The new rule proposes to give providers more discretion to determine when a bona fide medical emergency exists

• Proposed language states that patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency when a patient’s consent cannot be obtained

• The requirement to document in writing specific information related to the medical emergency is maintained
Research Ability to Link Data Sets

- The new regulation is proposing to permit linking of data sets that include patient identifying information if the data is:
  - From a federal data repository AND
  - Approved by an IRB

OCHIN’s Position
Initial reaction to Proposed 42 CFR Part 2

• Aligns with direction OCHIN has implemented to facilitate data sharing for Part 2 records and is progress

• Believe that clinicians need to have complete patient information at point of care, and unclear that will improve

• Focus on Data Segmentation for Privacy (DS4P) initiative raises some practical questions about ability of technology vendors to build that into design of products and still provide integrated systems

Initial reaction to Proposed 42 CFR Part 2 (Continued)

• Many BH/SUD programs have not implemented certified technology because of the lack of meaningful use incentive payments.

• We think the lack of information sharing makes a SUD patient who seek treatment more vulnerable, not less, than those who don’t seek treatment.

• Implementation of new Final Rule will take time
Questions?

Thank You!

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