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Office of Alcoholism and
Substance Abuse Services

New York State Bar Association

Health Law Section Fall Meeting 2018
Transformation of the Health Care Delivery
Model: Practical Legal Guidance

Data Sharing/ Data Use Agreements

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Agenda

1. Population Health (Robert Kent)
2. Opioid Treatment/Recovery and Care Coordination (Rob)
3. DSRIP Collaborative (Rob)
4. Laws that Apply (Elaine)
 - a. HIPAA (Elaine)
 - b. 42 CFR Part 2 (Rob)
 - c. State Laws - Substance Abuse and Mental Health Laws (Rob)
5. Drafting Documents
 - a. Participation Agreements, Business Associate Agreements and Data Use Agreements (Elaine)
 - b. Authorizations and Consents (Rob)
6. IT and security issues (Elaine)
7. Ethical Considerations (Elaine & Rob)

Population Health (Robert Kent)

The Challenge – Transforming the Delivery System

There is a focus on transitioning:

From fragmented and overly focused on inpatient care → integrated and focused on outpatient care

From a re-active and siloed system → pro-active, community and patient-focused system

Build upon the Medicaid Redesign Team (MRT) - DSRIP.

DSRIP Collaboratives (Rob)

- Delivery System Reform Incentive Payment Program (DSRIP) is a major effort to collectively and thoroughly transform the New York State (NYS) Medicaid Healthcare Delivery System.
- 25 Performing Provider Systems (PPS) statewide.
- The DSRIP program goal - 25 percent reduction in avoidable hospital use over five years.
- The \$8 billion Medicaid reinvestment.

Opioid Treatment/Recovery and Care Coordination (Rob)

- OASAS system:
 - Treat 240,000 annually
 - 100,000 in treatment daily
- Opioid epidemic:
 - 72,000 overdose deaths nationally in 2017
 - 3,600 overdose deaths in NYS in 2017
- Only 1 of 10 in need get treatment

Laws that Apply (Elaine)

1. Laws that Apply

- a. HIPAA (Elaine)
- b. 42 CFR Part 2 (Rob)
- c. State Laws - Substance Abuse and Mental Health Laws (Rob)

HIPAA (Elaine)

- Types of Data – PHI, De-Identified Data, Limited Data Sets
- Types of Entities - Covered Entities, Business Associates, and Other types
- Business Associate Provisions
- Data Aggregation
- Limited Data Sets and Data Use Agreements
- Payment, Treatment, and Health Care Operations

Categories of Health Data under HIPAA

- Protected Health Information (“PHI”)
- De-Identified Health Information
- Limited Data Sets

Types of Entities under HIPAA

- Covered Entities – health plans, health care clearinghouses and providers that conduct electronic transactions
- Hybrid Entities
- OHCAs
- Business Associates

BUSINESS ASSOCIATE 45 CFR 160.103

- Business Associate is defined:
 - Except as provided in paragraph (4), (e.g. government agency), a business associate means with respect to a CE, a person who:
 - On behalf of such CE or an OHCA...creates, receives, maintains or transmits PHI for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing or...

Business Associates performing Data Aggregation

- Business Associate Contracts: A contract between the CE and the BA must:
 - Establish the permitted and required uses and disclosures of PHI by the Bas. The contract may not authorize the BA to use or further disclose the PHI by the Bas. The contract may not authorize the BA to use or further disclose the information...if done by the CE, except that:
 - (A) the contract may permit to the BA to use or disclose PHI for proper management and administration of the BA
 - (B) the contract may permit the BA to provide data aggregation services related to the health care operations of the CE.

DATA AGGREGATION

- Data aggregation means, with respect to PHI created or received by a BA in its capacity as the BA of a CE, the combining of such PHI by the BA with the PHI received by the BA in its capacity as a BA of another CE, to permit data analyses that relate to the Health Care Operations of the respective CEs.

Limited Data Sets

- A CE may use or disclose a limited data set...only for the purposes of research, public health or health care operations
- A CE may use PHI to create a limited data set...or disclose PHI only to a BA for such purposes, whether or not the limited data set is to be used by the CE.

DATA USE AGREEMENT

- A CE may use or disclose a limited data set...only if the CE obtains satisfactory assurance, in the form of a data use agreement ... that the limited data set recipient will only use or disclose the PHI for limited purposes.

DATA USE AGREEMENT - CONTENTS

- DATA USE AGREEMENT MUST:
 - Establish the permitted uses and disclosures of such information by the data set recipient,... The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the CE;
 - Establish who is permitted to use or receive the limited data set; and
 - Provide the limited data set recipient with...(see next slide)

DATA USE AGREEMENT

- Provide the limited data set recipient will:
 - Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement
 - Report to the CE any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
 - Ensure that any agents to whom it provided the limited data set agrees to the same restrictions and conditions that apply to the limited dataset recipient with respect to such information; and
 - Not identify the information or contact the i

Payment, Treatment & Health Care Operations

- Payment
- Treatment
- Health Care Operations

42 CFR Part 2 (Rob)

- In general, Part 2 Programs are prohibited from disclosing any information that would identify a person as having or having had a SUD unless that person provides written consent.
- Intended to ensure that a patient receiving treatment for a SUD does not face adverse consequences in relation to issues such as criminal proceedings and domestic proceedings such as those related to child custody, divorce or employment.
- Limited exceptions.

State Laws - Substance Abuse and Mental Health Laws (Rob)

- NYS Confidentiality law – Section 33.16 of the Mental Hygiene Law.
- 42 CFR Part 2 supersedes.

Drafting Documents

- Participation Agreements
 - Designed to ensure that participants comply with the data sharing policies and procedures, explain the terms of the relationship including roles, rights and responsibilities of each party.
- Business Associate Agreements
 - Person or entity that performs certain activities involving the use or disclosure of PHI on behalf of, or provides services to a Covered Entity;
- Data Use Agreements
 - A Covered Entity may use or disclose a limited data set if that entity obtains a data use agreement from the recipient.

Authorizations and Consents (Rob)

- Advice – searching for exceptions is not a good investment of time.
- OASAS has developed consent forms – provider trust.
- <https://oasas.ny.gov/mis/forms/trs/index.cfm>
- Recent update – developed a universal consent form with Healthix in Staten Island.

IT and security issues (Elaine)

- Conducting vendor assessments
- HIPAA Security Requirements
- Ensuring Encryption in Transmission and at Rest

Ethical Considerations (Elaine & Rob)

- What information are we talking about?
- Why 42 CFR Part 2 is still relevant?

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