

Legal, Ethical and Structural Aspects of Data Sharing: AISP Frameworks and Relevant Laws

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Florida Commission on Mental Health and Substance Abuse Meeting Data Subcommittee -- April 10, 2024

Agenda

- Review of interim Report Recommendations
- Quality Framework for Integrated Data Systems
- Legal Considerations for Data Integration
 - Authority and Structure
 - Legal Agreements
 - MOUs, DSAs, DULs and Consent
 - Relevant Federal and State Laws
 - FERPA
 - HIPAA
 - 42 CFR Part 2
 - Florida Medical Record laws
 - Florida Data Collaboratives
 - Florida Digital Bill of Rights (goes into effect July 1, 2024)
- Resource Links

Interim Report “Data” Recommendations

- Establish a Data Analysis Workgroup
- Secure administrative authority and commitment from stakeholders and state agencies (DCF, AHCA, etc)
- **Determine structure of repository (centralized, federated, etc) as well as policies and protocols for data standardization, security, access and resources**
- Implement a pilot
- Identify and evaluate areas of necessary improvement

Quality Framework for Integrated Data Systems (AISP)

Five key components of quality that set successful efforts apart:

1. Governance
2. Legal
3. Technical
4. Capacity
5. Impact

https://aisp.upenn.edu/wp-content/uploads/2021/11/Final_AISP_QualityFramework_11.5.21.pdf



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Legal Considerations for Data Integration

- **Authority and Structure**
 - Technology, Policies and Staff (training/education)
- **Legal Agreements (documents for relationships)**
 - MOUs
 - DSAs
 - DULs
 - Consent

Guidance and templates: https://aisp.upenn.edu/wp-content/uploads/2022/06/AISP_Finding-A-Way-Forward_Final_6.16.2022.pdf

Legal Considerations for Data Integration

- **Relevant Federal and State Laws**
 - FERPA
 - HIPAA
 - 42 CFR Part 2
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FERPA

- Protects the confidentiality of education data
- Generally need **consent** to disclose, but there are 3 broad **exceptions**:
 - Perform an institutional service or function that an employee would otherwise perform
 - To audit or evaluate a federal or state education program
 - To conduct a study to develop, validate or administer tests, aid programs or improve instruction
- If **deidentified** or just **Directory Information**– also can share/integrate.

Note -- Because researchers often had difficulty accessing records protected by FERPA, the U.S. DOE promulgated a rule intended to expand access for research making clear that “these final regulations allow FERPA-permitted entities to disclose PII from education records without consent to authorized representatives, which may include other state agencies, **or to house data in a common state data system, such as a data warehouse administered by a central state authority** for the purposes of conducting audits or evaluations of federal- or state-supported education programs.” Fed Register, 2011, 76(NO.232, p75637

- FERPA Flowchart: <https://aisp.upenn.edu/wp-content/uploads/2023/05/FERPA-Flowchart.pdf>



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HIPAA

- Protects against inappropriate disclosure of private healthcare data by “covered entities”.
- Generally need **consent**/authorization to disclose, but several **exceptions**:
 - To conduct Public health activity (monitoring, preventing abuse, etc) or safety intervention (prevent pandemic, etc)
 - Provide health oversight (audits, compliance checks, etc)
 - For Treatment, Payment or Operations (TPO)
 - To conduct research (w/waiver of authorization by IRB, etc)
- If **deidentified** – also can share/integrate.
- HIPAA also provides for creation of a “**limited data set**” as an alternative to the use of PHI.
- Can also receive data as a **Business Associate**.
- HIPAA Flowchart: <https://aisp.upenn.edu/wp-content/uploads/2023/05/HIPAA-Flowchart.pdf>



42 CFR, Part 2

- Prohibits the disclosure and use of patient substance abuse records unless certain circumstances exist.
- Generally need **consent** to disclose, but several relevant **exceptions**:
 - Medical Emergencies
 - Research (in accordance with HIPAA and other restrictions)
 - To a business associate, etc
 - To scientific researcher
 - Audit and Evaluation
- If **deidentified** – also can share/integrate
- So, data sharing is allowed with appropriate agreements and safeguards under 42 CFR Part 2 and recent changes in Feb 2024 align it more with HIPAA (not as onerous).

Florida Medical Records

Fla Stats §395.3025 Patient and personnel records; copies; examination.—(1) Any licensed facility shall, upon written request, ... furnish, in a timely manner ... to any person admitted therein for care and treatment or treated there at, ... a true and correct copy of all patient records,...

- (2) This section does not apply to [psychiatric hospitals]...
- (3) This section does not apply to {substance abuse treatment}...
- (4) Patient records are confidential and must not be disclosed without the consent of the patient or [legal representative], but appropriate disclosure may be made without such consent to:

...

- (a) Licensed facility personnel, attending physicians, or other health care practitioners and providers currently involved in the care or treatment of the patient for use only in connection with the treatment of the patient.
- (b) Licensed facility personnel only for administrative purposes or risk management and quality assurance functions.
- (c) The agency, for purposes of health care cost containment.

...

Florida Data Collaboratives FL Stats §163.6

“COLLABORATIVE CLIENT INFORMATION SYSTEMS

- 163.61 “Agency” defined.
- 163.62 Collaborative client information system; establishment.
- 163.63 Steering committee; security policy information sharing agreements.
- 163.64 Sharing of client information.
- 163.65 Agencies receiving government funding encouraged to participate.”

“**163.62 Collaborative client information system; establishment.—**

Notwithstanding any general or special law to the contrary, the agencies of one or more local governments may establish a collaborative client information system. State agencies and private agencies may participate in the collaborative information system. Data related to the following areas may be included in the collaborative information system, although the system is not limited to only these types of information: criminal justice, juvenile justice, education, employment training, health, and human services.”

FL Digital Bill of Rights

- Signed by Governor in 2023, goes in effect 7/1/24.
- The FDBR imposes obligations on for profit legal entities that conduct business within the state of Florida, which collect personal data from consumers, and have an annual global revenue of more than \$1 billion (among other requirements), **to obtain consumer consent before selling the consumer's sensitive data.**
- **HOWEVER**, it does not apply to certain classes of data, including health records and health related data, scientific research data, data subject to 42 CFR Part 2, etc – almost all data that this initiative would want to access (See SB 262, Section 7 or FS §501.704).

Resources

Actionable Intelligence for Social Policy (AISP)

- Actionable Intelligence for Social Policy (AISP) is an organization housed at the University of Pennsylvania that is focused on helping state and local governments collaborate and responsibly use data to improve lives. AISP has established a network of local and state-wide data integration initiatives from across the country which can share insights, structures and legal agreements. <https://aisp.upenn.edu>
- Relevant Reports:
 - *Quality Framework for Integrated Data Systems* provides discussion of 5 key components of quality that set success integrated data system apart. https://aisp.upenn.edu/wp-content/uploads/2021/11/Final_AISP_QualityFramework_11.5.21.pdf
 - *Finding a Way Forward: How to Create a Strong Legal Framework for Data Integration* provides a roadmap (including legal templates) to support exchanging, linking, and using data across government agencies. https://aisp.upenn.edu/wp-content/uploads/2022/06/AISP_Finding-A-Way-Forward_Final_6.16.2022.pdf

