

Data Sharing and the Law

Deep Dive on Consent



Data sharing initiatives can be hyper-local, but they are all subject to the same federal laws regarding privacy and consent. Working through Data Sharing Consent or Release of Information forms can be almost frightening in this highly regulated landscape. During a Deep Dive workshop at the 2018 All In: Data for Community Health [National Meeting](#), attorneys from the Network for Public Health Law explored when consent may or may not be the key to sharing data and how policies

and regulations governing health care, education, and behavioral health data like HIPAA, FERPA, and 42 CFR Part 2 impact consent. The Colorado Regional Health Information Organization (CORHIO) shared insights from the Colorado Advanced Interoperability Initiative deploying a SAMHSA-sponsored, open-source Consent2Share consent management platform. This workshop proceedings report shares some of the key themes that engaged participants.

Key Takeaways

When is consent required?

It depends!

What are the legal considerations for building consent forms?

While there are many laws to navigate as you begin thinking about multi-sector data sharing, in general:

1. Protection only applies to individually identifiable information
2. Individually identifiable information can only be disclosed with the individual's consent, unless an exception applies

Note: Data can have all personal identifiers removed and still, at times, an individual might be identified through geographic identifiers, dates, unique characteristics or conditions, or a combination of characteristics.

It is crucial to make consent processes simple enough for patients and clients to fully understand, with all information necessary for people to make informed decisions about what they are agreeing to disclose. In developing consent or release of information forms, it is important to ask three questions about the disclosure in question:

1. "Can I (share this data)?" - What does the law *allow*?
2. "Must I?" - What does the law *require*?
3. "Should I?" - How should I exercise my discretion? Even if it is legal to share data, what are the ethical implications of the situation?

What do I have to include in my consent form?

Many laws have required elements and notices - for example, [compare the "consent checklists" for HIPAA vs 42 CFR Part 2 vs FERPA](#). Look for the exceptions and provisions for specific purposes as you draft your form.

TIP: Make sure your consent forms refer to bidirectional exchange between organizations, or among multiple parties if there are additional partners.

What about FERPA and data sharing regulations for children?

FERPA and other relevant regulations can make HIPAA look like a walk in the park! However, while FERPA often requires consents (e.g., schools cannot share student immunization records with public health unless there is a health emergency such as an outbreak), it is possible to have very simple permission slips that allow parents to opt in to sharing between the school and relevant public health departments or providers (e.g., on the first day of school get permission to share information about things like immunization records).

Do I need to obtain written consent?

Consent for disclosure of information can be obtained through oral, written, and electronic methods. Thanks to the Uniform Electronic Transactions Act, electronic consents carry the same weight as written paper consents.

- **Question:** Does the ability to print or store electronic record of consent have to be automatic, or upon request?
- **Answer:** The Uniform Electronic Transactions Act does not specify - it should be automatic and would be best practice to make it available upon signing. Clients should be able to go online and pull it when they want to.

What should I keep in mind when requesting data?

Data standards and responsibilities are often applicable if an organization is receiving federal funding that comes with requirements (e.g., if an organization receives WIC funding, it is then responsible for managing WIC data in compliance with WIC regulations). Those used to working with those regulations may have the impression that they apply more broadly.

- **Question:** Sometimes when we request the same set/type of data, different hospitals have different processes/requirements for the data we have requested - what is our responsibility?
- **Answer:** You have a responsibility to accurately and fairly represent what you want to receive, your legal authority to receive it, and to use it in a manner consistent with any data use or other agreements and consistent with legal requirements. Generally, absent mandatory reporting requirements, it is the provider of the data who is responsible for disclosing data to you in compliance with law and establishing the terms for data sharing.

Where can I find examples of good data sharing agreements or consent forms?

The National Neighborhood Indicators Partnership has a [catalog of example data-sharing agreements](#). The Network for Public Health Law also has a [group resource library](#) on the *All In: Data for Community Health* online platform where folks are encouraged to upload their own examples or templates!

What is Consent2Share?

[Consent2Share](#) is a free, off-the-shelf, open source software application that allows patients to decide which health information they would like to share with their health care providers through an online consent process.

What is the experience of communities who have used Consent2Share?

The software will likely require investment of additional time and resources to make it work for your particular organization. It makes sense to spend some time with your IT experts before choosing to deploy Consent2Share. In Colorado, patients were generally more comfortable with their physician guiding them through the consent process than using a platform on their own.

Do you have any recommendations for sharing behavioral health data?

In CORHIO's pilot testing of two processes to share behavioral health data with providers, a few clear lessons learned emerged:

1. Automate existing workflows. Pushing information directly to providers through the EHR is more effective than asking them to retrieve data from a separate location.
2. Make it easy for Community Mental Health Centers to share their 42 CFR Part 2 data, no matter how they interpret the rule.
3. In general, clients want to share important data with all of their treating providers. They do not want to be bothered with approving every instance of sharing; as a rule, they would rather everyone see everything, unless they have an exception.

TIP: A Qualified Services Organization Agreement (QSOA) is like a BAA between substance use treatment providers, allowing agreeing entities to share substance use data freely

What kinds of information are covered by 42 CFR Part 2?

Substance use information is not categorically covered by 42 CFR Part 2. For example, generally:

Is this covered under 42 CFR Part 2?	Yes	No
Screening and referral services		X
Community health centers		X
Providers who administer Medication Assisted Treatment to patients and their treatment notes	X	
Hospitals		X
Hospital detox units	X	

TIP: The Substance Abuse and Mental Health Services Administration (SAMHSA) has compiled [many more examples and FAQs](#) about disclosure of substance use disorder patient records.

SUMMARY OF RELEVANT RESOURCES

- [Deep Dive workshop slides](#): Review the slides from the Deep Dive workshop on consent at the *All In* National Meeting.
- [NNIP's Collection of Example Data Sharing Agreements](#): Explore examples and templates of data sharing agreements and MOUs between various sectors.
- [Network for Public Health Law group](#): Join this group on the *All In* online community and access resources shared by members.
- [Consent elements comparison chart](#): Compare consent requirements for HIPAA, 42 CFR Part 2, and FERPA.
- [Consent2Share](#): Learn more about this open source software application for obtaining consent from patients.
- [SAMHSA 42 CFR Part 2 FAQs](#): Read about applying substance abuse confidentiality regulations to health information exchange.

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ABOUT DATA ACROSS SECTORS FOR HEALTH (DASH)

DASH, a national program of the Robert Wood Johnson Foundation led by the Illinois Public Health Institute in partnership with the Michigan Public Health Institute, aims to align health care, public health, and other sectors to systematically compile, share, and use data to understand factors that influence health and develop more effective interventions and policies. DASH and its partners in [All In: Data for Community Health](#) are creating a body of knowledge to advance this emerging field by identifying and sharing lessons learned, promising practices, and indicators of progress.

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ABOUT THE NETWORK FOR PUBLIC HEALTH LAW

The Network for Public Health Law (Network), a national initiative of the Robert Wood Johnson Foundation, provides technical assistance, along with resources and training to public health officials, practitioners, advocates and attorneys so that they can make full use of the law as a tool to improve health outcomes. Organizations and individuals committed to improving public health can [join the Network](#) at no cost.

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