42 CFR Part 2: Improvements and New Challenges with the Use and Disclosure of Substance Use Disorder Treatment Records

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Presenters:
Adam Greene
Rebecca Murow Klein
Jennifer Lohse

Moderator:
Shannon Hartsfield Salimone
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Shannon Hartsfield Salimone is a health lawyer whose practice focuses on corporate compliance, particularly in the regulatory and data privacy areas. She is Board Certified in Health Law by the Florida Bar Board of Legal Specialization and Education. She advises clients on state and federal matters, including healthcare compliance, internal investigations, HIPAA and data privacy, cyber liability and reducing risk, consumer protection relating to privacy, long-term care, fraud and abuse, licensure, EMTALA, meaningful use of electronic medical records and prescription drug distribution. Mrs. Salimone is a past Chair of the ABA Health Law Section’s eHealth, Privacy & Security Interest Group.

<table>
<thead>
<tr>
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Agenda

• Background on the Part 2 Rule
• 2017 Amendments – The Good and the Bad
• The View from a Part 2 Program
• Q&A
Rebecca Murow Klein

**Rebecca Murow Klein** joined the Association for Behavioral Health and Wellness (ABHW) in 2013. As the Director of Government Affairs, she leads the organization’s efforts to inform state and federal policy makers on issues related to behavioral health, including telemental health, health care integration, and parity implementation. Rebecca chairs the Partnership to Amend 42 CFR Part 2, a coalition that is advocating to align 42 CFR Part 2 with HIPAA for the purposes of health care treatment, payment, and operations. Before joining ABHW, Rebecca served as Legislative Assistant for Health and Education Policy in the office of Senator Ben Nelson (D-NE). She holds a B.A. from the University of Michigan.
Adam H. Greene

Adam Greene, a nationally-recognized authority on HIPAA and the HITECH Act, primarily counsels health care systems and technology companies on compliance with the HIPAA privacy, security, and breach notification requirements. Adam is a former regulator at the U.S. Department of Health and Human Services (HHS), where he played a key role in administering and enforcing the HIPAA rules. At HHS, Adam was responsible for determining how HIPAA rules apply to new and emerging health information technologies and he was instrumental in the development of the current enforcement process.

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Practice
• Health Information Privacy, Security, and Breach Response

Education
• George Washington University, J.D.
• George Washington University, M.P.H., Epidemiology
• Johns Hopkins University, B.A., Biology

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• District of Columbia
Jennifer Lohse joined the Hazelden Betty Ford Foundation in 2014 as Vice President, General Counsel and Corporate Secretary, and is responsible for the legal, risk management, and compliance functions. She routinely advised on state and federal matters, including healthcare compliance, billing matters, internal investigations, corporate matters, governance, HIPAA and 42 CFR Part 2, fraud and abuse, licensure, mandated reporting, and other matters concerning operations.

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<thead>
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42 CFR PART 2: FEDERAL SUBSTANCE USE PRIVACY REGULATIONS
Background

• Authorization
  – Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970
  – Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972

• Intent
  – Provide protection to individuals undergoing treatment for substance use disorders
  – Encourage people to seek treatment without fear of prosecution by law enforcement and government
Overview

- 42 CFR Part 2 regulations relate to the confidentiality of substance use disorder patient records and apply to:
  - Federally funded individuals or entities that “hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or treatment referral, including units within a general medical facility that hold themselves out as providing diagnosis, treatment or treatment referral”

- 42 CFR Part 2 does not allow for disclosures without written consent
  - Consent requirements
  - Re-disclosure
  - Limited exceptions

- 42 CFR Part 2 is not enforceable
Recent SAMHSA efforts to Modify 42 CFR Part 2

• Proposed Rule
  – Published February 9, 2016
  – Intended to modernize 42 CFR Part 2 rules by:
    – Facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes
    – Ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder

• Final Rule
  – Published January 18, 2017, effective March 21, 2017
  – Makes some modifications, but does not go far enough

• Supplemental Notice of Proposed Rulemaking
Changes in final rule

• New option for general designation in “to whom” section of consent form
• Changes to “from whom” section
• Research requirements more consistent with HIPAA research requirements
• Prohibition on re-disclosure remains
• Patient information can be disclosed without consent to medical personnel in event of a medical emergency
• Definition of Qualified Service Organizations (QSOs) expands
Partnership to Amend 42 CFR Part 2: Goals and Next Steps

• 29 partner organizations
• Align 42 CFR Part 2 with HIPAA for TPO, maintain protections that currently exist
• Final rule does not go far enough
• Legislative fix is necessary
2017 AMENDMENTS: THE GOOD AND THE BAD
The Good

• Allows for consent to include an intermediary (e.g., *XYZ Health Information Exchange*) and “general designation” for treating providers, e.g., “my past, current, and future treating providers).

• Increased a provider’s discretion to determine when a “bona fide medical emergency” requires disclosure of Part 2 records

• Provided increased flexibility, including to non-Part 2 programs, to disclose Part 2 records for research.

• Provided additional flexibility related to disclosures for audits and evaluation, including related to ACOs.

• Supplemental Notice of Proposed Rulemaking, if finalized, would provide non-Part 2 programs with significantly increased ability to appropriately use and disclose Part 2 records.
### Table 1—Designating Individuals and Organizations in the “To Whom” Section of the Consent Form

<table>
<thead>
<tr>
<th>42 CFR 2.31</th>
<th>Individual or entity to whom disclosure is to be made</th>
<th>Treating provider relationship with patient whose information is being disclosed</th>
<th>Primary designation</th>
<th>Required additional designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)(4)(i)</td>
<td>Individual</td>
<td>Yes</td>
<td>Name of individual(s) (e.g., Jane Doe, MD).</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(4)(i)</td>
<td>Individual</td>
<td>No</td>
<td>Name of individual(s) (e.g., John Doe)</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(4)(ii)</td>
<td>Entity</td>
<td>Yes</td>
<td>Name of entity (e.g., Lakeview County Hospital).</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(4)(iii)(A)</td>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is a third-party payer as specified under §2.31(a)(4)(iii)(A) (e.g., Medicare).</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(4)(iii)(B)</td>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is not covered by §2.31(a)(4)(iii)(A) (e.g., HIE, or research institution).</td>
<td>At least one of the following: 1. The name(s) of an individual participant(s) (e.g., Jane Doe, MD, or John Doe). 2. The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (e.g., Lakeview County Hospital). 3. A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed (e.g., my current and future treating providers).</td>
</tr>
</tbody>
</table>
The Bad

• If consent includes a “general designation” for treating providers, then:
  − Consent must identify an individual's right to receive a list of all disclosures (including TPO) that identifies receiving providers by name.
  − Part 2 program must provide the list of disclosures upon request.
The Bad

• Consent must include “[h]ow much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.”
  - “It is permissible to include ‘all my substance use disorder information’ as long as more granular options are also included.”
  - “The types of information that might be requested include diagnostic information, medications and dosages, lab tests, allergies, substance use history summaries, trauma history summary, elements of a medical record such as clinical notes and discharge summary, employment information, living situation and social supports, and claims/encounter data.”
The Bad

• Notice of privacy practices must be amended to include contact information for enforcers of Part 2 Rule:
  – U.S. Attorney’s Office for relevant judicial district(s)
  – If opioid treatment program, then also:
    SAMHSA Center for Substance Abuse Treatment
    5600 Fishers Lane
    Rockville, MD 20857
    240-276-1660
THE VIEW FROM A PART 2 PROGRAM
Disclaimer

• There are many views from Part 2 programs, and different experiences…..

this is one.
Hazelden Betty Ford Foundation

- Nation's largest nonprofit alcohol and drug addiction treatment provider
- 17 treatment sites, 9 states
- Fully accredited graduate school
- Research center
- Prevention program across the nation and in 50+ countries
- Publishing house dedicated to behavioral health topics
Are you a Part 2 Program?

• See § 2.12
• Federally Assisted
• Substance Use Disorder Program
  – What services are being performed?
  – What services are being marketed?
• See also: definition of when an individual becomes a “patient”
Disclosures

• Need **written** patient consent to release information
  − Must be accompanied by a redisclosure notice
  − Consent may be revoked verbally
  − Patient cannot “waive” Part 2 requirements
  − Three different consent constructs
    1. Treating Providers
    2. Third Party Payors
    3. Everyone else
Disclosures (continued)

• Very limited situations for disclosure without patient consent
  − No treatment, payment or health care operations exceptions
  − Only child abuse related mandated reporting
  − May conflict with required disclosures under state law (i.e. mandated reports under licensing regulations for vulnerable adult or Tarasoff warnings)
Qualified Service Organizations (QSO)

• Similar to business associates (defined by HIPAA), but with some significant differences:
  – BAAs may include the additional terms for a QSO Agreement
  – Silent on “down-stream” QSOs
  – Disclosure back to Part 2 program only
  – Cannot enter into QSOs with other non-Part 2 providers for care coordination
Other Considerations

• State privacy laws may be more stringent
• May have Part 2 compliance obligations if receive Part 2 information
• No state law preemption
• Regulators required to sign agreement for audit and inspection purposes
• Subpoena for records must be accompanied by either:
  − Patient consent
  − Compliant court order
Questions?
Thank You!

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