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HIPAA and SAMHSA: Harmonizing Substance Abuse Treatment and Privacy Goals -- A Critical Challenge

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Overview

- **SAMSHA (Substance Abuse and Mental Health Services Administration) Rules on Privacy of Patient Records**
  - Underlying Statute
  - Implementing Regulations (“Part 2” Rules)
  - Proposed Rule Modifications
- **HIPAA Privacy Rule**
  - Provisions Relevant to Care Coordination
  - HHS OCR Request for Information on Possible Modifications
- **Congress**
  - Policy objectives
  - Proposals
  - Political realities, obstacles, and opportunities

SAMSHA Part 2 Rules: Statutory Background and Key Regulatory Provisions

Statute Underlying Part 2 Rules

- **42 U.S.C. § 290dd-2: "Confidentiality of Records"**
- **Purpose**: to encourage patients to seek substance abuse treatment without fear of prosecution by law enforcement or other adverse action
- **Criminal Prohibition**: makes it a crime to disclose patient records held in connection with federally assisted substance abuse treatment except:
  - with the patient's written consent;
  - to medical personnel to address a medical emergency
  - for research or audits *without patient identifiers*; or
  - pursuant to a court order after good cause is shown

Implementing Regulations: 42 C.F.R. Part 2 -- Scope

- Restrict use and disclosure of records containing patient identifying information that are created or received by a Part 2 Program
  - Part 2 Program: federally assisted individual or entity (and dedicated staff thereof) providing substance use disorder ("SUD") diagnosis, treatment, or referral for treatment
  - "Patient": individual who has sought or received a diagnosis, treatment, or referral for treatment for a SUD
  - Patient identifying information: any information identifying a patient (other than a number assigned to a patient by a Part 2 Program for internal use only)
- Restrictions on disclosures also apply to recipients of protected records, including non-Part 2 Program SUD treatment providers

Permissible Disclosures of SUD Patient Records

- SAMHSA Regulations prohibit disclosure of SUD patient identifying information except:
  - as statutorily permitted (*i.e.*, with patient written consent; in a medical emergency; or pursuant to a court order with a showing of due cause), or
  - to report suspected child abuse or neglect, or crime at a Part 2 Program
  - to a "Qualified service organization" (QSO): entity or individual providing services to a Part 2 Program who has agreed in writing to:
    - comply with the Part 2 Rules
    - resist in judicial proceedings any efforts to obtain access to SUD-related patient identifying information

What Is Needed for Patient Written Consent?

- Name of patient
- Name or other designation of Part 2 Program permitted to make disclosure
- Explicit description of SUD information that may be disclosed
- Specific identification of authorized recipient(s) (*not general categories such as HIPAA permits*)
- Purpose of disclosure
- Statement that consent is subject to revocation at any time
- Date, event or condition for expiration of consent
- Signature of patient or authorized representative
- Date of signing

Obstacles to Care Coordination

- Without patient consent, disclosures for treatment may only be made:
  - to medical personnel to meet a bona fide medical emergency
  - emergency must be one that precludes obtaining patient's prior informed consent
- Consent requirements are so detailed they may prevent sharing of patient records for beneficial treatment
- QSO Agreements may not be used for "care coordination"
  - Can use QSO Agreements for "medical staffing services" (*e.g.*, to provide on-call coverage services) but not "medical services" such as contacting patient's primary care provider (which would involve sharing patient SUD information)
- All requirements carry threat of criminal penalties for impermissible disclosures

SAMSHA Proposed Part 2 Modifications
(August 2019)

Care Coordination Objectives

- Respond to opioid crisis and need for treatment to prevent overdose deaths

- Facilitate care coordination, including between Part 2 programs and other providers

Proposed Modifications

- Encourage sharing of patient SUD information among Part 2 Programs and other providers by clarifying that:
  - Part 2 disclosure restrictions apply only to SUD patient records originating with Part 2 Programs
  - Non-Part 2 SUD treatment providers can segregate records subject to Part 2 from other records (such as notes from meeting with patient)
- SAMHSA: "This level of flexibility is needed in order to improve coordination of care efforts, and to save lives."

SAMHSA Proposal Limitations

- Does not permit disclosure of SUD patient information for care coordination as part of “health care operations”
  - Part 2 permits disclosures without patient consent to contractors, subcontractors and legal representatives for “health care operations” purposes
- SAMHSA proposal would amend Part 2 to expressly list examples of “health care operations” activities, subject to clarification that:
  - [these activities are] “not intended to cover care coordination or case management, and disclosures . . . to carry out such purposes are not permitted”
- SAMHSA expressly noted that “this policy differs from the [HIPAA] Privacy Rule, under which ‘health care operations’ encompasses case management and care coordination”

HHS OCR Request for Information
(December 2018)

Care Coordination Objectives

- “Promoting information sharing for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize, or require covered entities to disclose PHI to other covered entities.”
- “Encouraging covered entities, particularly providers, to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the opioid crisis.”

Relevant Privacy Rule Provisions

- HIPAA covered entity health care providers (“covered providers”) may disclose protected health information (“PHI”) without a patient authorization:
  - for **treatment** purposes:
    - to other health care providers, *including those not regulated by HIPAA*
    - without regard to the general “minimum necessary” standard
  - for **case management and care coordination**
    - as part of their own **health care operations** activities
    - for the recipient’s **health care operations** activities

OCR Observations

- The Privacy Rule permits, but does not require, covered entities to use and disclose protected health information (“PHI”) for treatment, payment or healthcare operations (“TPO”) purposes.
- There is no deadline or requirement to disclose records when requested by another health care provider or other covered entity for purposes of coordinating care or managing cases.
- This can lead to circumstances where records are not transferred between covered entities (or from a covered entity to another health care provider) in a timely fashion, to the detriment of coordinated care and/or case management.

OCR Questions: Should Providers be Required to Share PHI to Enhance Care Coordination?

- Do health care providers currently face barriers or delays when attempting to obtain PHI from covered entities for treatment purposes?
  - For example, do covered entities ever affirmatively refuse or otherwise fail to share PHI for treatment purposes or unreasonably delay sharing PHI for treatment purposes?
- Should covered entities be required to disclose PHI when requested by another covered entity for treatment or healthcare operations purposes?
- Would such a requirement improve care coordination and/or case management?
- Should any limitation be placed on such a requirement, such as applying it only apply to certain health care operations purposes?

OCR Questions: What About Part 2?

- How would a general requirement for covered health care providers to share PHI when requested by another covered health care provider interact with other laws, such as 42 CFR part 2, that require patient consent?
- Under any such requirement, should the requesting covered entity have to obtain the patient's explicit authorization before initiating the request?
- What Privacy Rule changes could help address the opioid epidemic? What risks are associated with these changes?
  - For example, is there concern that encouraging more sharing of PHI in these circumstances may discourage individuals from seeking needed health care services?
  - Would encouraging more sharing of PHI interfere with individuals' ability to direct and manage their own care?
  - How should OCR balance the risk and the benefit?

OCR Observations

- The Privacy Rule allows covered entities to disclose PHI to caregivers in certain circumstances, including certain emergency circumstances, and this permission has particular relevance today in relation to the opioid crisis.
- But anecdotal evidence suggests that some covered entities are reluctant to inform and involve the loved ones of individuals facing such substance abuse and mental health crises for fear of violating HIPAA.
- This reluctance may hinder effective coordination of care and case management involving caregivers, including family members and friends.

OCR Questions: What Privacy Rule Amendments Would Help Foster Non-Professional Care Coordination?

- Should the Privacy Rule allow disclosures of PHI to non-covered entities who are not health care providers for care coordination purposes?
- What types of non-health care providers are key to care coordination and patient assistance?

OCR Questions: Are Privacy Rule Changes Needed to Give Parents More Care Coordination Opportunities?

- Are there circumstances in which parents have been unable to gain access to their minor child's health information, especially where the child has substance use disorder (such as opioid use disorder) or mental health issues, because of HIPAA?
- Could changes to the Privacy Rule help ensure that parents are able to obtain the treatment information of their minor children, especially where the child has substance use disorder (including opioid use disorder) or mental health issues?
- If the Privacy Rule is modified, what limitations on parental access should apply to respect any privacy interests of the minor child?

Congress:
Can Legislation Achieve Solutions?

Confidentiality Coalition

A broad group of organizations working to ensure that we as a nation find the right balance between the protection of confidential health information and the efficient and interoperable systems needed to provide the very best quality of care.

Members

AdventHealth
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State Farm
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Surescripts
Teladoc
Texas Health Resources
UCB
UnitedHealth Group
Vizient
Workgroup for Electronic Data Interchange
ZS Associates

What's the problem to be solved?

- Better coordinate care for treating people with substance use disorders (SUDs) while maintaining confidentiality of SUD patients' records

- Lack of information about SUDs among care providers and coordinators leads to safety risks for individuals with SUDs

- Better flow of information is necessary to save lives
  - Part 2 regulations should be modernized to align with the HIPAA privacy and security rules

Is aligning Part 2 with HIPAA technically feasible for policymakers to undertake?

- Lack of revision for decades
  - Part 2 regulations had not been updated since 1987
  - SAMHSA's August 2019 proposed regulations would not change the fundamental structure of Part 2's confidentiality requirements
- Technical feasibility
  - Does SAMHSA have the authority to make meaningful changes to Part 2?
  - If not, Congress must step in –"Overdose Prevention and Patient Safety Act" has been introduced (H.R 6082) and passed by large majority in House (357-57)

What about political viability and economic feasibility?

- Political viability
  - Broad support from families and caregivers, providers and health plans, patient support groups
  - Opposition from some addiction recovery support groups
  - H.R. 6082 passed US House of Representatives with overwhelming majority vote
  - Senate is making strides toward re-introduction of Protecting Jessica Grubb's Legacy Act
  - Trump Administration's *Regulatory Sprint to Coordinated Care* agenda
- Economic feasibility
  - Cost of opioid epidemic/other substance use disorders to society
  - No CBO scores on legislation

Alternatives?

- No action means continuation of the status quo – does this deserve consideration?
- Could OCR make adjustments through forthcoming HIPAA NPRM?
- SAMHSA's 2019 proposed rules would only tweak around the edges
- Legislative alternatives to Senate language:
  - Require initial informed consent
  - Expand anti-discrimination provisions
    - Access to treatment
    - Termination of employment
    - Receipt of workers' comp
    - Rental housing
    - Social services and benefits
  - Collaborative rulemaking

What's politically feasible?

- Current legislative language is not feasible for key committee leader in US House
- Administration is finding it difficult to allay specific concerns
  - Child custody
  - Provider discrimination
- Feasible - Legislative alternative to what has already passed the U.S. House of Representatives that includes compromises to satisfy key concerns from stakeholders
  - One-time consent at outset, then align with HIPAA
- Target date is May 2020 to pass this year

Where are we now?

- Stakeholders fervently lobbying Congress
- Waiting for agreement on compromise legislation regarding initial consent to then align with HIPAA
- Mark-up of new language scheduled for March 3 in Senate HELP Committee
- AMA appears to have reversed its position to support alignment of Part 2 with HIPAA (June 2019 statement)
- If compromise language is agreed to, what is the vehicle for movement in Congress?
- Awaiting HIPAA NPRM to see if creative alternatives are proposed

Questions?

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