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lpettit@himss.org
LTPAC Roundtable: Series

• To provide LTPAC IT leaders (providers, vendors and academia) with a forum for informing HIMSS North America (HNA) on ways the HNA society can help;
  – advance the adoption and use of health information technologies within LTPAC provider organizations,
  and
  – advocate LTPAC’s IT needs and concerns to external healthcare IT organizations (e.g. acute-care providers; HIT vendors; policymakers).
LTPAC Roundtable: Calendar

2016

9/13/2016
Engaging LTPAC Providers in Hospital Care Coordination Efforts: The Why and How

10/11/2016
Care Coordination and Person-Centric Longitudinal Care

11/15/2016
The Challenges of Care Coordination Involving Behavioral Health data: A Panel Discussion

12/13/2016
Care Coordination and Analytics: Hospitals and LTPAC Data-Driven Partnerships

2017

1/10/2017
Care Coordination and Transitions of Care

2/14/2017
De-coding 42 CFR Part 2: Understanding the New Regulations' Impact on Care Coordination

3/14/2017
Critical Analysis of Care Coordination in Different LTPAC Settings

4/11/2017
Care Coordination and Behavioral Health Services

5/9/2017
Care Coordination and Connected Health

6/13/2017
Preview of LTPAC HIT Summit
LTPAC Roundtable: Agenda

HIMSS17: LTPAC Related Activities
Lorren Pettit, Vice President, HIS, HIMSS North America

De-coding 42 CFR Part 2: Understanding the New Regulations' Impact on Care Coordination
Michael R. Lardieri, LCSW
Assistant Vice President, Strategic Program Development
Behavioral Health Service Line
Northwell Health

Kimberly A. Johnson, Ph.D
Director, Center for Substance Abuse Treatment (CSAT)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Renée M. Popovits, J.D.
Principal Attorney, Popovits Law Group, P.C.
LTPAC/Care Coordination
Suggested Activities

Long-Term and Post-Acute Care Roundtable

The Long-Term and Post-Acute Care (LTPAC) Roundtable helps shape the direction of HIMSS in serving the needs of LTPAC providers and vendors. The LTPAC Roundtable meetings focus on topics relevant to the LTPAC IT community, to include professional development, public policy initiatives, interoperability, and the value of health IT.

**LTPAC at HIMSS17** - Interested in LTPAC activities at HIMSS17? [Here's a list of suggested LTPAC educational sessions and activities.](#)
LTPAC/Care Coordination
Suggested Activities

TUESDAY, February 21st

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<tr>
<th>Time</th>
<th>Activity</th>
<th>Session #</th>
<th>Room</th>
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<tbody>
<tr>
<td>7:30 - 8:30 am</td>
<td>Long-Term and Post –Acute Care (LTPAC) Breakfast</td>
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<tr>
<td>8:30 - 9:30 am</td>
<td>Post-Acute Integration: Lowering Risk, Lowering Cost</td>
<td>65</td>
<td>W208C</td>
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<td>9:00 am - 6:00 pm</td>
<td>HIMSS17 Exhibition</td>
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<td>10:00 am - 5:00 pm</td>
<td>POSTER SESSION: Continued Access to Hospital Patient Health Record Data in Long Term Care</td>
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<tr>
<td>10:00 - 10:30 am</td>
<td>Longitudinal Care Plans – Part 1</td>
<td>KC44</td>
<td>Booth 5179</td>
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<td>11:30 am - 12:30 pm</td>
<td>21st Century Success in Transitions of Care Communication</td>
<td>95</td>
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<tr>
<td>1:00 - 1:30 pm</td>
<td>Longitudinal Care Plans – Part 2</td>
<td>KC44</td>
<td>Booth 5179</td>
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<tr>
<td>1:00 - 2:00 pm</td>
<td>Enhancing Community Mental Healthcare Delivery with IT</td>
<td>109</td>
<td>W207C</td>
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<tr>
<td>1:00 - 2:00 pm</td>
<td>Care Coordination Transformation: Road to Population Health</td>
<td>112</td>
<td>W304A</td>
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<td>1:30 - 1:30 pm</td>
<td>ONC / LTPAC Stakeholder meeting (invite only)</td>
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<td>2:30 - 3:30 pm</td>
<td>Senior Care Trending: Tech Case Study for Population Health</td>
<td>125</td>
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<tr>
<td>2:30 - 3:30 pm</td>
<td>It’s Not Always About Technology: Effective Coordinated Care</td>
<td>134</td>
<td>W331A</td>
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<tr>
<td>3:45 - 4:15 pm</td>
<td>HIMSS Analytics: Continuity of Care Maturity Model (CCMM) Overview</td>
<td>134</td>
<td>Booth 2133</td>
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<tr>
<td>5:00 - 5:20 pm</td>
<td>Data Capture and Management in Behavioral Health</td>
<td>IH30</td>
<td>Booth 3361</td>
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<tr>
<td>6:00 - 7:00 pm</td>
<td>Long-Term Care Community Reception</td>
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WEDNESDAY, February 22nd

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<td>8:30 - 9:30 am</td>
<td>Connecting Senior Care: Wearables and Analytics Drive Results</td>
<td>141</td>
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<td>9:30 am - 10:00 am</td>
<td>HIMSS17 Exhibition</td>
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<tr>
<td>10:00 - 11:00 am</td>
<td>Maximizing Behavioral Health Care Delivery: Reviewing Real World Challenges and Opportunities</td>
<td>154</td>
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<td>10:00 - 11:00 am</td>
<td>Winning at Care Coordination Using Data-Driven Partnerships</td>
<td>166</td>
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<tr>
<td>10:45 - 11:15 am</td>
<td>Re-Imagining Effective Post-Acute Care Transitions</td>
<td>KC52</td>
<td>Booth 6179</td>
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<td>11:00 - 11:20 am</td>
<td>Bringing Connected Health Home for Older Adults</td>
<td>CH34</td>
<td>Booth 7281</td>
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<td>1:00 - 2:00 pm</td>
<td>Create Safe, Effective Automated Behavioral Health Services</td>
<td>188</td>
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<tr>
<td>2:15 - 2:45 pm</td>
<td>HIMSS Analytics: Continuity of Care Maturity Model (CCMM) Overview</td>
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<td>Booth 2133</td>
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<tr>
<td>3:15 - 4:15 pm</td>
<td>Behavioral HIE: Rural Best Practices</td>
<td>FH25</td>
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THURSDAY, February 23rd

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<td>8:30 - 10:00 am</td>
<td>Keynote Speaks: John Boehner &amp; Ed Rendell</td>
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<td>1:15 - 2:30 pm</td>
<td>Keynote Speakers: Robert Herjavec &amp; Kevin O’Leary</td>
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# LTPAC/Care Coordination  
**Sunday, February 19, 2017**

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<th>Time</th>
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<td>HIMSS17 Opening Reception</td>
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<td>A Universal Model for Pop. Health Management</td>
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<td>a. Mental Health &amp; HIE</td>
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<td>b. Care Coord. Transform.</td>
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De-coding 42 CFR Part 2: Understanding the New Regulations' Impact on Care Coordination

Michael R. Lardieri, LCSW
Assistant Vice President, Strategic Program Development
Behavioral Health Service Line
Northwell Health

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Director, Center for Substance Abuse Treatment (CSAT)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Renée M. Popovits, J.D.
Principal Attorney, Popovits Law Group, P.C.
Session Speakers

Michael R. Lardieri, LCSW  
AVP, Strategic Program Development  
Behavioral Health Service Line  
Northwell Health

Kimberly A. Johnson, Ph.D.  
Director, Center for Substance Abuse Treatment (CSAT)  
Substance Abuse and Mental Health Services Administration (SAMHSA)

Renée M. Popovits  
Principal Attorney  
Popovits Law Group, PC

HIMSS North America
"De-coding 42 CFR Part 2: Understanding the New Regulations' Impact on Care Coordination"

Michael R. Lardieri, LCSW
AVP Strategic Program Development
Behavioral Health Service Line
Northwell Health

2/14/17
Focus on Total Cost of Care
Behavioral Healthcare Costs in

Source: C. Boyd et al. Clarifying Multimorbidity Patterns to Improve Targeting and Delivery of Clinical Services for Medicaid Populations. Center for Healthcare Strategies Data Brief, December 2010
Move Towards Value Based Payments

PPACA & Market Price Pressure Set The Course Toward Pay-For-Value

Compensation Continuum By Level Of Financial Risk

Small % of financial risk  Moderate % of financial risk  Large % of financial risk

Fee-for-service  Performance-Based Contracting  Bundled & Episodic Payments  Shared Savings  Shared Risk  Capitation  Capitation + Performance-Based Contracting

No financial accountability  Moderate financial accountability  Full financial accountability

Management via 100% case by case external review  Internal ownership of performance using internal data management

Passive involvement  Provider engaged  Provider active in management  Providers assumes accountability

HIMSS North America
Care managers will guide the patient to the appropriate level of care

Without the Care Manager guide we cannot ensure patients use the Northwell system
Behavioral Health is Essential To Health

Prevention Works

Treatment is Effective

People Recover
Confidentiality of Substance Use Disorder Patient Records Final Rule (42 CFR Part 2)

Kimberly Johnson, PhD
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health & Human Services
CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS

This Proposed Rule document was issued by the Department of Health and Human Services (HHS). For related information, see the Open Docket Folder.

Action

Supplemental notice of proposed rulemaking.

Summary

On Feb. 9, 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rulemaking (NPRM) that proposed policy changes to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR part 2). SAMHSA explained in the NPRM that these changes were intended to better align the regulations with advances in the U.S. health care delivery system while retaining important privacy protections for individuals seeking treatment for substance use disorders. The last substantive update to these regulations was in 1987. SAMHSA is issuing this Supplemental Notice of Proposed Rulemaking (SNPRM) to propose additional clarifications to the part 2 regulations as amended by the concurrently issued final rule. As noted in the final rule, 42 CFR part 2 Confidentiality of
OVERVIEW OF PRESENTATION

- Background
- Notice of Proposed Rulemaking (NPRM)
- Final Rule
- Supplemental Notice of Proposed Rulemaking (SNPRM)
Modern version of the Hippocratic Oath:

“I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know.”

http://guides.library.jhu.edu/c.php?g=202502&p=1335759
ACCESS & QUALITY HINGE ON TRUST...

Cyberattacks on personal health records growing 'exponentially'

The Washington Post

ELECTRONIC HEALTH INFORMATION

HHS Needs to Strengthen Security and Privacy Guidance and Oversight

United States Government Accountability Office

Report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate

August 2016
Congress recognized that the stigma associated with substance use disorders and fear of prosecution deterred people from entering treatment, and enacted 42 CFR Part 2 to ensure an individual’s right to privacy and confidentiality.

For decades, the right to privacy & confidentiality has been a cornerstone of treatment programs across the country.

In this respect, 42 CFR Part 2 has been in the vanguard of personal privacy protections.
BASICS: 42 CFR Part 2

- Implements federal drug and alcohol confidentiality law (42 U.S.C. §290dd-2).
  - Protects confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research.
The law and regulations were written during a time of great concern about the potential use of substance use disorder information against an individual.

The purpose of 42 CFR part 2 is to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.
WHY REVISE 42 CFR PART 2?

- Regulations first promulgated in 1975 and last substantively updated in 1987.
- Significant changes have impacted health care delivery since then:
  - New models of integrated care that rely on information sharing to support coordination of patient care.
  - Electronic infrastructure for information exchange.
  - New focus on performance measurement.
CONSIDERATIONS IN REVISING 42 CFR PART 2

Breach of privacy of information protected by part 2 can still lead to civil and criminal consequences for patients, including:

• Loss of employment, housing, child custody.
• Discrimination by medical professionals and insurers.
• Arrest, prosecution and incarceration.
Importantly, the consequences of fewer and laxer privacy controls and regulations can disproportionately penalize minority, underserved, and otherwise marginalized populations.

- In this context, loosening privacy controls could *increase* rather than reduce health disparities, and *impede* rather than promote access.
LISTENING TO THE PUBLIC

SAMHSA held a Public Listening Session in 2014 to solicit feedback on 42 CFR Part 2.

- Approximately 1,800 individuals participated in the session (in person or by phone).
- SAMHSA received 112 oral comments and 635 written comments.

http://www.youtube.com/playlist?list=PLBXgZMI_zqfTRftyiS4ckNi9bYW4Vmj82
In addition to considering the wealth of public input received from the Listening Session, SAMHSA collaborated with its federal partner experts in developing the NPRM.

NPRM published in the Federal Register on February 9, 2016 (81 FR 6988).

Comment Period was 60 days and closed on April 11, 2016.

376 comments were received.
Final rule published in the Federal Register on January 18, 2017 (82 FR 6052).

Federal Register effective date initially scheduled for February 17, 2017.

Under review by the administration with a possible effective date of 3/20/17.

Snapshot of Final Rule Major Provisions
Final rule is intended to modernize the part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder.
SAMHSA finalized terminology changes throughout for clarity, consistency, and to modernize the regulations (e.g., from “alcohol and drug abuse” to “substance use disorder”).

• SAMHSA changed the name of the regulations to: **Confidentiality of Substance Use Disorder Patient Records.**
SAMHSA finalized its proposal to revise the requirement for reporting violations of part 2 by methadone programs (now referred to as opioid treatment programs) to the Food and Drug Administration (FDA) because authority over these programs was transferred from the FDA to SAMHSA in 2001.
SAMHSA finalized its proposals:

- Consolidate all but one definition in a single section (§2.11).
  - “Federally assisted” remains in the Applicability provision at §2.12 for the purpose of clarity.
- Modernize terminology and ensure consistency of use across regulations.
CLARIFY: EXISTING DEFINITIONS (§2.11)

SAMHSA finalized its proposals to revise/clarify several existing definitions:

- **Qualified service organization**
- **Central registry**
- **Patient**
- **Person**
- **Treatment**
SAMHSA finalized the following existing definitions with modifications:

- **Disclose**, to specifically cover diagnosis, treatment, and referral for treatment for a substance use disorder.
- **Maintenance treatment**, replaced the term “pharmacotherapy” with the phrase “long-term pharmacotherapy” for clarity.
- **Member program**, replaced a reference to a specific geographic distance.
• **Patient identifying information**, to make a clarification in the preamble discussion and two revisions to the regulatory text.

• **Program, did NOT** finalize the proposed changes regarding “general medical practices” but did make minor updates to terminology (see Applicability).

• **Records**, added “created by” to “received or acquired by a part to program...” and a parenthetical with examples of what constitutes a record.
SAMHSA finalized the following new definitions as proposed:

- *Part 2 program*, which is separate and distinct from the definition of *Program*.
- *Part 2 program director*, with a minor non-substantive technical edit.
- *Withdrawal management*. 
NEW DEFINITIONS (§2.11)

SAMHSA finalized the following definitions with modifications:

- *Substance Use Disorder*, except that the parenthetical of the proposed definition is not adopted in the final rule.

- *Treating provider relationship*, to account for involuntary commitments and other situations where a patient is diagnosed, evaluated and/or treated, but may not have actually consented to such care.
SAMHSA did not finalize its proposal to revise the definition of Program so that it would not apply to either “general medical facilities” or “general medical practices” in certain circumstances.

- These proposed revisions were not finalized because the addition of the term “general medical practice” was found to be unnecessary.
- Commenters also found the proposed revision confusing.
Consistent with SAMHSA’s previous FAQ guidance, a practice comprised of primary care providers could be considered a “general medical facility” and be subject to 42 CFR part 2 if they are both "federally assisted” and meet the definition of a program under § 2.11.
SAMHSA finalized its proposal to add a requirement that, upon request, patients who have included a general designation on their consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures).

• However, in the final rule, SAMHSA clarified that the entity that serves as an intermediary, *NOT the part 2 program*, is responsible for complying with the List of Disclosures requirement.
SAMHSA did not finalize its proposal to allow entities two years after the effective date of the final rule to comply with the List of Disclosures requirements.

- The right to obtain, upon request, a List of Disclosures is only available to patients who use a general designation in the “To Whom” section of the consent form.
• SAMHSA clarified in the Final Rule that the general designation on the consent form may not be used until entities have the ability to comply with the List of Disclosures provision.

→ SAMHSA plans to issue subregulatory guidance on this provision.
SECURITY FOR RECORDS (§2.16)

SAMHSA finalized its proposals to:

• Address both paper and electronic records.
• Clarify that both part 2 programs and other lawful holders of patient identifying information must have in place formal policies and procedures for the security of records, including sanitizing media associated with both paper and electronic records.
SECURITY FOR RECORDS (§2.16) (cont.)

- Must reasonably protect against unauthorized uses and disclosures of patient identifying information and protect against reasonably anticipated threats or hazards to the security of patient identifying information.

- Replace relevant language in other sections with reference to the policies and procedures requirement in §2.16.

- SAMHSA may provide subregulatory guidance on this provision.
SAMHSA modified this section from that proposed in the NPRM in response to comments; and revised the provision to allow for more flexibility in storing electronic records.

- SAMHSA made a distinction between electronic devices (something that has computing capability, such as a laptop, tablet, etc.) and electronic media (something that can be read on an electronic device, such as a CD/DVD, flash drive, etc.).
• SAMHSA also revised the language to allow one year to complete the process of sanitizing paper electronic media.
  ▪ This change should allow for select patient records to be removed from both the specific site and any operational sources without disrupting other patient records.
SAMHSA finalized its proposals to:

- Clarify that the written summary of federal law and regulations may be provided to patients in either paper or electronic format.
- Require the statement regarding the reporting of violations to include contact information for the appropriate authorities.
SAMHSA finalized its proposal to:

• Allow, in certain circumstances, a patient to include a *general designation* in the “To Whom” section of the consent form.
  
  ▪ Distinction between those with and without a treating provider relationship with the patient.

• Require an explicit description of the “Amount and Kind” of substance use disorder treatment information.
SAMHSA decided *not to finalize* its proposal to remove the general designation option in the “From Whom” section of the consent form, but did make minor updates to the terminology.

- The final “From Whom” provision of the consent requirements specifies that a written consent to a disclosure of patient identifying information must include the specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.
In the NPRM, SAMHSA proposed to require the consent form to include two new statements that the patient understands:

- the terms of their consent, *which was NOT finalised*.
- when using a general designation in the “To Whom” section, their right to obtain, upon request, a list of entities to whom their information has been disclosed, pursuant to the general designation (see §2.13), *which was finalised*. 
SAMHSA finalized its proposal to permit electronic signatures (to the extent that they are not prohibited by any applicable law).
SAMHSA finalized its proposal to clarify that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both, and allows other health-related information shared by the part 2 program to be re-disclosed, if permissible under other applicable laws.
SAMHSA made some additional minor clarifying revisions to §2.32 relative to:

- The use of general authorizations.
- The restrictions on using information to criminally investigate or prosecute a patient with a substance use disorder.
SAMHSA finalized its proposal to revise the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a “bona fide medical emergency” exists.

In response to comments, SAMHSA plans to issue subregulatory guidance addressing this provision, including examples of what constitutes a “bona fide medical emergency.”
In the NPRM, SAMHSA proposed to allow a part 2 program or other lawful holder of patient identifying information to disclose part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule).
SAMHSA finalized this proposal with certain modifications:

- § 2.52(a) clarifies that lawful holders may re-disclose part 2 data for research purposes, subject to the other conditions imposed in § 2.52.
- § 2.52(a)(2) clarifies that disclosure of part 2 data also is permitted for research that qualifies for exemption under the Common Rule due to the lower risk to subjects in circumstances where exemptions apply.
In the NPRM, SAMHSA proposed to address data linkages to enable researchers holding part 2 data to link to data sets from federal data repositories provided certain conditions were met.

- SAMHSA revised this provision in the final rule to enable researchers holding part 2 data to link to data sets from federal and non-federal data repositories provided certain conditions are met.
  - Supports more advanced research, including studies of longitudinal effects of patient treatments.
SAMHSA finalized its proposal to address the retention and disposal of part 2 data used in research by referencing expanded §2.16, Security for Records.

SAMSHA plans to issue additional subregulatory guidance on the Research provision.
SAMHSA finalized its proposals to:

- Include provisions for both paper and electronic patient records.
- Permit the part 2 program, not just the part 2 program director, to determine who is qualified to conduct an audit or evaluation.
- Update Medicare and Medicaid audit or evaluation section to include Children’s Health Insurance Program (CHIP).
• Permit an audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (including CMS-regulated Qualified Entities).
  ▪ Modified slightly to include certain language changes (e.g., evaluations by CMS “or its agents”, and Participation Agreement “or similar documentation”)
• Revise requirements for destroying records by referencing expanded §2.16, Security for Records.
In addition to the final rule, SAMHSA issued a SNPRM on January 18, 2017 (82 FR 5485).

- Seeks to obtain additional comments and information on some additional proposed clarifications to 42 CFR part 2.

CLARIFICATIONS

Comments must be received:

• Federal Register: no later then 5 pm on February 17, 2017

Instructions for submitting comments are in the SNPRM on page 5485.

SNPRM OVERVIEW: PERMISSIBLE DISCLOSURES

- SAMHSA is issuing this SNPRM in response to public comments received on the NPRM that addressed specific changes not proposed in the NPRM.
- These comments led SAMHSA to propose additional clarifications and modifications to the part 2 rules to clarify the scope of permissible disclosures.
Comments highlighted varying interpretations of the rule's restrictions on lawful holders and their contractors' and subcontractors' use and disclosure of patient identifying information for purposes of carrying out payment, health care operations, and other health care related activities.

- Third-party payers, other lawful holders, and their contractors and subcontractors and legal representatives play a critical role in the provision of health care services.
42 CFR PART 2 SNPRM: SNAPSHOT OF MAJOR PROVISIONS
Specifically, SAMHSA seeks comment on the following proposed provisions:

- § 2.32 (Prohibition on Re-disclosure) – to consider whether an abbreviated notice would be appropriate and in which circumstances

- § 2.33 (Disclosures Permitted with Written Consent) – to define and limit the circumstances in which certain disclosures for the purposes of payment and health care operations can be made
PROPOSED PROVISION: § 2.53

- § 2.53 (Audit and Evaluation) - to expressly address further disclosures by contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or CHIP audit or evaluation
SAMHSA does not propose to substantively modify the existing notice at 2.32, but seeks comment on whether it should add an abbreviated notice to accompany re-disclosure for use in certain circumstances where a shorter notice may be warranted.

- For example, “Data is subject to 42 CFR part 2. Use/disclose in conformance with part 2.”
Disclosures Permitted With Written Consent (§2.33): Patient Identifying Information (PII)

SAMHSA proposes to explicitly list and limit under § 2.33(b), specific types of activities for which any lawful holder of patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities.

- Lawful holders may disclose patient identifying information to contractors, subcontractors, and legal representatives for the purposes described in the list of activities.
Disclosures Permitted With Written Consent (§2.33): PII & Required Consent

- List of activities is similar to HIPAA Privacy Rule's definitions of “payment” and “health care operations,” but excludes those related to diagnosis, treatment, or referral for treatment (e.g., care coordination or case management).
- Consent is required, and contractors, subcontractors, and legal representatives must perform a function that is consistent with the stated purpose of the consent and only use the information to perform that function.
Disclosures Permitted With Written Consent (§2.33): PII and Contractors & Subcontractors

SAMHSA proposes new regulatory text under § 2.33(c) requiring that lawful holders that engage contractors and subcontractors to carry out payment and health care operations that will entail using or disclosing patient identifying information include specific contract and subcontract provisions requiring contractors and subcontractors to comply with the provisions of part 2.

- Appropriate comparable instrument will suffice in cases involving a legal representative.
SAMHSA solicits comment on whether the proposed listing of explicitly permitted activities is adequate and appropriate to ensure the health care industry's ability to conduct necessary payment and the described health care operational functions, while still affording adequate privacy protections.
SAMHSA seeks comments on the proper mechanisms to convey the scope of the consent to lawful holders, contractors, subcontractors, and legal representatives, including those who are downstream recipients of patient identifying information given current electronic data exchange technical designs.
SAMHSA proposes to revise the Audit and Evaluation provision to address the following issues raised by commenters:

- Contractors, subcontractors, and legal representatives may be tasked with conducting audit and evaluation activities.
- Such entities may not be CMS-regulated, and audits may be conducted for private payers as well as Medicare and Medicaid programs.
• Audits and evaluations may include quality improvement activities, as well as efforts related to reimbursement and financing.
The new proposals and clarifications discussed in this SNPRM are intended to provide the desired solutions and understanding sought by commenters to the NPRM, while also offering patient protections appropriate to the current health care environment.

The payment, health care operations, and audit and evaluation functions discussed in the SNPRM will be subject to other applicable laws and regulations, in addition to 42 CFR part 2. (e.g., the HIPAA Privacy and Security Rule).
The fact that lawful holders and part 2 programs are permitted to disclose data in no way obviates:

- The purpose of part 2 to protect patient identifying information for patients seeking diagnosis, treatment, or referral for treatment for substance use disorders
- The responsibility lawful holders and part 2 programs have to exercise due diligence with respect to their contractors, subcontractors, or legal representatives to whom they disclose or with whom they exchange patient identifying information.
FURTHER GUIDANCE

- SAMHSA anticipates issuing further guidance addressing any revisions or clarifications to part 2 that stem from this SNPRM.
ADDITIONAL REQUESTS FOR PUBLIC COMMENTS

SAMHSA seeks specific comments on the implications of these proposed changes on:

- The overall goals of the part 2 rules
- The privacy and confidentiality of records concerning substance use disorder diagnosis, prognosis, treatment, and referral for treatment
  - Including the establishment of appropriate restrictions and safeguards on lawful holders and their contractors, subcontractors, and legal representatives’ use and disclosure of patient identifying information for purposes discussed in this SNPRM.
SAMHSA also seeks specific comments on the regulatory and financial impacts, if any, of the proposed revisions.
Further, SAMHSA seeks comments on the following for its consideration in future rulemaking and guidance:

- Additional purposes for which lawful holders should be able to disclose patient identifying information, and

- Additional subregulatory guidance that SAMHSA and other agencies could provide to facilitate implementation of 42 CFR part 2 in the current health care environment.
SAMHSA is not soliciting comments on any other issues relating to the final rule and will not consider comments at this time that address changes to part 2 other than those contemplated in this SNPRM.
FINAL RULE AND SNPRM NEXT STEPS

SAMHSA will:

- Develop subregulatory guidance.
- Develop additional webinars, other presentations, and outreach materials.
- Review SNPRM comments received by the deadline and determine how to move forward.
- Consistent with the 21st Century Cures Act, within one year of issuing the 42 CFR part 2 final rule, “convene relevant stakeholders” to discuss its effect on “patient care, health outcomes, and patient privacy.”
42 CFR Part 2 and other regulations provide ground rules, but how these rules are applied to ensure privacy and the best care requires careful analysis and monitoring.

- Who needs what information when?
- Who determines who needs what information when?
- What are the consequences & outcomes?
- And more...
CLOSING THOUGHTS: CONSENT2SHARE

https://www.samhsa.gov/health-information-technology/samhsas-efforts
QUESTIONS OR COMMENTS?

THANK YOU,
Kimberly.Johnson@samhsa.hhs.gov
Polling Question #1

To facilitate needed information sharing and care coordination, do you believe the new Part 2 Final Regulations:

A. Allows too much information sharing
B. Improves information sharing and care coordination
C. Hinders information sharing and care coordination
D. No change from previous regulation
E. Unsure
Perceptions of Protection

Renée M. Popovits
Principal Attorney
Popovits Law Group, PC
February 14, 2017
Roadmap for Presentation

- Truth on Enforcement
- Consent and List of Disclosures
- Sub-regulatory Guidance
- Opioid Crisis and Central Registries
- Data implications: Care Coordination, Population Management and Research
- Security, Portability and Confidentiality
- Looking to the Future
Perception Becomes Reality

• Rule has been in existence for 42 years
• Providers and HIEs believe significant restrictions to information sharing
• Patients believe their information is protected
• Raise our consciousness—be aware of the rule's limits
• It’s time to see the forest through the trees
The Truth About Enforcement

- In 1992, the original confidentiality statutes were eliminated and re-codified
- In new 290dd-2 statute, specific penalties were removed and only reference Title 18
- No specific mention of felony, misdemeanor or infraction so no notice of amount of criminal penalty
- No SUD confidentiality law offenses exist in Title 18
- New Part 2 criminal penalty section eliminated the specific fines: See 2.3
- US Attorney is responsible for prosecution. US Attorney Manual Section 1872 reference fines in old statute which no longer exist
- Criminal statutes strictly construed in favor of potential violator: See 2.2(b)(3)
- No reported prosecutions over the 40 plus years
- No private right of action; no state attorney general enforcement; no exclusion from evidence protections
- Patients believe protections exist which do not; they deserve the truth and the statute needs to be fixed
- Only a perception of protection exists
Program Notice Requirement 2.22

• Must provide patient written summary of federal confidentiality requirements

• **NEW:** Notice can be written or electronic

• Include among other things a statement “violation of federal law and regulations by a Part 2 program is a crime”

• **NEW:** Inform patient that violations may be reported to US Attorneys Office in the district where you are located and include contact information
Additional Enforcement Questions

• If not a Part 2 program, how does US Attorney have jurisdiction over non programs?
• Does US Attorney have jurisdiction over “lawful holders”?
• US Attorney would need to prove beyond a reasonable doubt a violation occurred
  – If ambiguity exists in the regulation, more difficult to prove
  – If ambiguity exists in penalty provisions, US Attorney may choose not to prosecute
Consent

- Positive expansion to allow a General Designation in the "To Whom" provision
- This can include current and future providers
- Additional language required in consent
- Different rules for “treating providers”
- List of disclosures requirements
- Pay attention to “amount and kind of information”
- Rule changes will require updates to consent forms and IT systems
Treating Provider Relationship

**DEFINITION**

- A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, **AND**;

- The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition

  - “Agrees” does not necessarily imply a formal written agreement; could be making an appointment by a telephone call
  - Begins when an individual seeks or receives health-related assistance from an individual or entity who may provide assistance
  - Clearly established when the individual or entity agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, **whether or not there has been an actual in-person encounter**
  - When a patient is not competent or involuntary committed, treating provider relationship MAY be established when a patient is, agrees to or is legally required to be provided consultation
  - Includes any member of the health care team
List of Disclosures (2.13)

• List of disclosure required: If use general designation in consent for **non-treating providers** (third party payers, entities that facilitate health information exchange, research entities or entities that serve as intermediaries)

• Disclosures made in last two years

• Include name of entity to which disclosure made, date of disclosure & brief description of information disclosed

• HIPAA Security Rule technical safeguard considerations
Polling Question # 2

Do you think that technology exists to provide patients the required list of all disclosures?

A. I believe the technology can provide this today
B. Technology cannot provide it today but will be able to do this in the next 2-3 years
C. Technology is not and will not be capable of tracking all required disclosures
D. Unsure
Sub-regulatory Guidance

• Interpretative guidance is exempt from Administrative Procedures Act (enforcement guidance, FAQs, agency manuals, opinion letters and interpretative bulletins)

• Courts required to give deference to agency’s interpretation of own rule

• Force of law question

• Over 20 references to sub-regulatory guidance in Final Rule so many issues still open to interpretation

• Covers a variety of topics: applicability, consent, list of disclosures, technical solutions, treating providers, medical emergency, re-disclosure, lawful holders, audit and evaluation, research, compliance with HIPAA security requirements and enforcement/penalties
Applicability: As Clear as Mud

- A lot of discretion
- EAPs are now included
- Hold themselves out test
- Medical practice provision restricted but not clear
- Statute is broader on applicability than Part 2
Central Registries

  - 22.5 Million have used an illegal drug in prior year
  - 20.8 million met criteria for a substance use disorder
  - 66.7 million have admitted to binge drinking at least once a month
  - 18.9 million reported misuse of prescription drugs (12.5 million of which are pain relievers)

- In light of national opioid crisis and increased use of medicated assisted treatment, need to pay attention to disclosures to Central Registry, withdrawal management or maintenance treatment

- New definition of central registry

- Revised provisions in 2.34 consent for disclosures to prevent multiple enrollment
Updated Security Requirements 2.16

- Security applies to paper and electronic records
- New policies and procedures required
- Provision regarding maintaining information and removing patient identifiers
- Not clear if that applies after the record retention period or at all times information rests on system
- May provide sub-regulatory guidance on whether compliance with HIPAA Security satisfies 2.16
Data Linkages and Research

- Researchers holding Part 2 data can link data sets from federal and non-federal data repositories
- Must comply with 2.52
- Changes predicated on existing Human Subjects Protections in Common Rule promulgated in 1991
- What is impact of new Human Subjects Rule released on 1.19.17
Qualified Service Organizations (QSO)

• QSO allowed for population management
• QSO now restricted to medical staffing services not medical services generally
• QSO not allowed for care coordination because it has a patient treatment component
• Population health management is “increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group.”
• To achieve the best outcomes providers must supply proactive, preventive and chronic care to all their patients, both during and between encounters with the health care system. For patients with SUDs who often have comorbid conditions proactive, preventive and chronic care is important to achieving desired outcomes.
• QSO is limited to offices or units responsible for population health management (ACO, CCO, CPCMH, MCO) not the entire organization and not participants
• Can’t share with case managers, physicians, addiction counselors, hospital and clinics, need Part 2 consent
• Can’t permit multi-directional sharing of information
Portability vs Privacy

- HIPAA simplifies administrative procedures and facilitates the PORTABILITY of health information
- Part 2 addresses CONFIDENTIALITY to encourage people to seek treatment
Select HIPAA and Confidentiality Provisions in 21st Century Cures Act

- Bi-partisan legislation signed December 13, 2016. Title XI- Compassionate Communication on HIPAA
- Sec. 11001. Sense of Congress
  - The Sense of Congress finds that clarification is needed regarding existing permitted uses and disclosures of health information under the Health Information Portability and Accountability Act (HIPAA) by health care professionals to communicate with caregivers of adults with SMI to facilitate treatment.
- Sec. 11002. Confidentiality of Records
  - Requires the Secretary to, within a year of finalizing updated rules related to the confidentiality of health records related to alcohol and drug abuse, convene relevant stakeholders to determine the effect of the regulation on patient care, health outcomes, and patient privacy.
- Sec. 11003. Clarification on Permitted Uses and Disclosures of Protected Health Information
  - Directs the Secretary through the Director of the Office for Civil rights to clarify circumstances when a health care provider or covered entity may use or disclosure protected health information related to the treatment of an adult with a mental or substance use disorder.
- Sec. 11004. Development and Dissemination of Model Training Programs
  - Requires the Secretary to identify or recognize private or public entities to develop model training and educational programs to educate health care providers, regulatory compliance staff, and others regarding the permitted use and disclosure of health information under HIPAA.
Looking to the Future

• Update the statute to provide clarity on information sharing that benefits patients and better health outcomes; fix enforcement issues; and enhance patient protections.

• Integrate new protections of SUD records within the HIPAA Privacy Rule so it applies to covered entities (not be limited to Part 2 Programs); take the best of Part 2; and eliminate separate rule. This will promote simplicity and consistency for all providers treating SUDs.

• Submit comments to SNPRM due on 2.17.17
The rules shall be applied equally and justly to all persons.

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Discussion

Michael R. Lardieri, LCSW
AVP, Strategic Program Development
Behavioral Health Service Line
Northwell Health

Kimberly A. Johnson, Ph.D.
Director, Center for Substance Abuse Treatment (CSAT)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Renée M. Popovits
Principal Attorney
Popovits Law Group, PC
Announcements: Next LTPAC Roundtable

**TOPIC:**
Critical Analysis of Care Coordination in Different LTPAC Settings

**MARCH 14, 2:00 pm CST**