Welcome & Housekeeping

- All stakeholders in New Mexico’s healthcare community are welcome
- We will record today’s webinar
- Lines will be muted as we begin
- To comment or to ask a question, please ‘raise your hand’ and unmute your line, or
- Direct your question or comment (to everyone, to the presenter, or to the host) in the chat box
Agenda

• **News & Information** – Thomas East, PhD, CEO/CIO; and Michelle Bowdich, Director of Outreach & Communications

• **Prize Drawing Winner Announcement**

• **Special Presentation:** *CFR 42 Part 2 and Patient Consent* – Mitchell Berger, MPH, Office of Policy, Planning and Innovation, Substance Abuse and Mental Health Services Administration (SAMHSA) and Suzette Brann, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA)

• **User Tip: Webinar Recordings** – April Salisbury, Director of Education and Training

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**NMHIC News & Information**

Thomas East, PhD

*CEO/CIO, LCF Research and NMHIC*
Behavioral Health

- We can share most behavioral health data now with a consent document that explicitly states that behavioral health data could be included in HIE.
- Data from Federally funded substance abuse treatment facilities requires a much higher level of consent management (42 CFR part 2). At this point we cannot accept data from these organizations. Orion will have their Security 2.0 model in production in 2017 that will support this.
- **Our recommendation:** Start with clinical portal access to see the rest of patient’s medical care, notifications for emergency department and inpatient admissions and Direct Secure messaging for exchange of information directly with primary care, hospital or other specialist.

NMHIC News – Behavioral Health

Collaborations Underway

- Santa Fe Behavioral Health Alliance
- Federally Qualified Health Centers
- SAMHSA SOAR
- Bernalillo County/City of Albuquerque
  - Behavioral Health Special Projects/Criminal Justice
- NM Corrections
- NM Sentencing Commission
- Rio Arriba County Care Pathways
- HSD, MCOs, and Others
Privacy and Security

• Information within the NMHIC HIE is subject to Federal and State Privacy and Security Regulations which includes HIPAA, HITECH and other regulations.
• Information is encrypted at rest and in transit.
• Access is limited to authorized users only.
• Insomnia Security has done penetration testing on our NMHIC Orion environment
• British Telecom America has done an external HIPAA audit
• Security meets industry standards such as SSAE16 (auditing), ISO 27001 and EHNAC

NMHIC News & Information

Michelle Bowdich
Director of Outreach and Communications
NMHIC HIE Participants

- 19 Hospitals Providing Data*
- 4 EDs Using Portal
- > 20 Provider Groups
- NM Medicaid
- 3 Laboratories
- Commercial Payer Organizations
- 1 Home Health
- 3 Diagnostic Imaging Organizations
- 1 Pharmacy
- 28 Hospitals and 9 Reference Laboratories send public health reporting
- NM Primary Care Assoc. Representing FQHCs

*Additional hospitals are signed up and/or in the queue

NMHIC welcomes additional stakeholders including: more home health, hospice, skilled nursing facilities, behavioral health, professional healthcare associations and ancillary service providers.

NMHIC News

New Organizations in contract discussions:
- NM Orthopedics

New Data Feeds:
- Artesia General Hospital (in process)
- Memorial Medical Center (in process: ADT, Labs, Radiology)
- Taos Holy Cross (interfaces from their new EHR in testing, including a new one for Radiology)
- Lovelace Health System (Most of their old interfaces are migrated over to their new EPIC EHR. Notes interface is in development.)
- New Mexico Cancer Center
- Radiology Assoc. of Albuquerque - Reports (in development)
- True Health and Anthem are now sharing their rosters.

INHOUSE Development
Saves ≈ $3K/interface
And provides flexibility
NMHIC News – New Participants

GILA REGIONAL MEDICAL CENTER
Silver City, NM

NMHIC News – New Participants

ASSURED IMAGING
Healthcare in Motion – X-Rays, Mammography, Bone Density Scanning [DEXA], Heart Health, Skin Cancer, and other screenings
Albuquerque, Las Cruces, Los Lunas
NMHIC News – Southern NM Outreach

• Las Cruces – Doña Ana County’s first Boxer March in Las Cruces, a Screen to Save Initiative (Sat. March 24, 10 am-1 pm) to increase colorectal cancer awareness and provide free colorectal cancer screening kits.
• La Clinica de Familia - Interested
• St. Luke’s Health Care - Interested
• IPA of Southern NM - Interested
• Others

NEW HIE Advisory Committee Members

• James Lilly, Deputy CIO, NM HSD
• Meggin Lorino, Executive Director, NM Association for Home & Hospice Care
• Dusadee Sarangarm, MD, Associate CMIO, UNM ED
• Julie Ann Harrigan, MD, Ardent Enterprise Physician Informatics Advisory
NMHIC News – Southern NM Outreach

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- IPA of Southern NM - Interested
- Others

Thank you for returning your NMHIC HIE Conference Survey!
Prize Drawing Winner...

Martha Hatfield, CCRC
Health IT Specialist, South Region, Pfizer

amazon $50 Gift Card


**CFR 42 Part 2 and Patient Consent**

Mitchell Berger, Office of Policy, Planning and Innovation, Substance Abuse and Mental Health Services Administration (SAMHSA)

Suzette Brann, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA)
Overview of 42 CFR Part 2: Confidentiality of Substance Use Disorder Patient Records

Mitchell Berger and Suzette Brann
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

DISCLAIMER

This presentation is not intended to constitute legal advice. Any examples discussed are for illustrative purposes only. All questions about compliance with 42 CFR Part 2, HIPAA and other applicable state and federal laws and requirements should be directed to an individual’s, agency’s or organization’s legal counsel.
Confidentiality of SUD Records: Statute and Regulation

- Congress noted in 1970s discrimination associated with substance use disorders (SUDs) and fear of prosecution deterring people from entering treatment
- At that time most SUD treatment provided by specialty providers
- Authorizing statute for confidentiality of SUD patient records regulations intended to ensure an individual’s right to privacy and confidentiality.
- Persons with SUDs continue to need appropriate protections to prevent misuse of medical information related to substance use

Confidentiality of SUD Records: Statute and Regulation

- Initial Part 2 regulations promulgated July 1, 1975.
42 U.S.C. § 290dd-2 is the basis for 42 CFR Part 2 regulations, and can only be changed by Congress:

- “Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States” shall be confidential
- May be disclosed as permitted by prior written consent of the patient
- Subject to certain exceptions/exclusions

Exceptions to consent requirement:

- To medical personnel to the extent necessary to meet a bona fide medical emergency
- To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation but individual patients cannot be identified by those personnel in any report or otherwise disclosed
- If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm)
- Except as authorized by court order, no record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient
Statute: 42 U.S.C. § 290dd-2

- Statute does not apply to:
  - Exchange of records within the Department of Veterans Affairs or between the VA and the Uniformed Services. VA to issue regulations and coordinate with HHS
  - Reports under state law of suspected child abuse or neglect
- Penalty: Violations fined under Title 18 of US Code
- Instructs HHS Secretary to promulgate regulations
- These regulations known as “42 CFR part 2” or “part 2”
- CFR=Code of Federal Regulations

A Framework for Understanding Part 2

Applicability: Is information covered/protected by Part 2 (§§2.11-2.23)?

Exceptions: If so covered, does it fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?

Consent: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Court orders: If no exception/exclusion to Part 2 applies and patient does not consent to disclosure, can a court order be obtained (§§2.61-2.67)?

Definitions (§2.11)

**Substance Use Disorder**: replaced *Alcohol abuse* and *Drug abuse* (2017 rule)

- A cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For this regulation, does not include tobacco or caffeine use

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**Definitions (§2.11)**

**Patient**: individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a part 2 program. 2017 rule updated terminology and added that the definition includes both current and former patients

**Records**: any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). Explicitly includes electronic records

**Treatment**: care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient

**Part 2 program**: federally assisted and meets definition of ‘program’
A Framework for Understanding Part 2 - Applicability

These regulations impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of any part 2 program (§2.2)

Regulations apply to any information, whether or not recorded, which “[w]ould identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person” (§2.12)

A Framework for Understanding Part 2 - Applicability

Applicability is fact-specific so is hard to generically state whether a given program is or is not a Part 2 program but key questions include:

A. Is the program **federally assisted**?
   - Program carried out under license, certification or registration by federal department or agency

   Ex. participating in Medicaid or Medicare; being authorized to conduct maintenance treatment or withdrawal management (42 CFR Part 8); registration under Controlled Substances Act to dispense medication-assisted treatment (e.g. DEA number)
### A Framework for Understanding Part 2 - Applicability

- Federal assistance also means supported by federal funding to states or local governments or directly
- Being tax-exempt or receiving tax-deductible donations
- Conducted in whole or part, directly or via contract, by federal entity

### B. Is a unit/entity/individual other than a general medical facility a Part 2 Program

1. Do they “hold themselves out” as providing diagnosis/treatment/referral for SUD?

   - Licensed/certified/registered to provide these activities
   - Advertisements, notices or statements about such services
   - Consultation activities about such services
A Framework for Understanding Part 2 - Applicability

For services provided by specialized staff in general medical facilities:

2. If a general medical facility, are services provided by an identified unit within the general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment?

3. For medical personnel or other staff in a general medical facility or practice, is their primary function to provide SUD diagnosis/treatment/referral and are they identified as providers of such services by the facility/practice?

General medical facility - ex. Hospital, FQHC, trauma center

A Framework for Understanding Part 2 - Exceptions and Exclusions

Some exceptions to consent, each of which has various caveats, qualifications and limitations, include:

- Bona-fide medical emergencies (§2.51)
- Audit and Evaluations (§2.53)
- Research (§2.52)-final rule aligns with HIPAA and Common Rule
- Disclosures to prevent multiple enrollments in maintenance or withdrawal programs within 200-mile radius (§2.34)
- Communications are within a part 2 program; or between a part 2 program and an entity that has direct administrative control over the program (§2.12)
- Disclosure to patient themselves ((§2.23)
Consent must be in writing and requires 9 elements including:

1. Must include name of patient
2. Amount and Kind: How much and what kind of information to be disclosed - should not just say “all my substance use disorder information” or “all of my records”
   Also should be granular options or categories such as diagnostic information, medications, employment information, trauma history, allergies. Can use checkboxes next to categories.
3. Purpose of disclosure (e.g., “treatment”)
4. ‘From whom’: Name of specific entity/individual permitted to make the disclosure
   ➔ 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.
5. ‘To Whom’ Name of individual(s) to whom disclosure is to be made or name of entity (if treating provider relationship exists)
6. Date, event or condition upon which consent will expire. Must ensure consent will last no longer than necessary to serve purpose for which it is provided
7. Other elements- notice that consent can be revoked (except to extent person/entity making disclosure has already relied on it)
8.-9. Patient signature and date when signed.
   ➔ Consent can be paper or electronic.
A Framework for Understanding Part 2-Consent

• ‘To Whom’ Name of individual(s) to whom disclosure is to be made or name of entity (if treating provider relationship exists)

• If treating provider relationship, name of individual provider or entity or general designation—“my current treating providers”

• Treating provider relationship—patient is or agrees to be diagnosed/evaluated/treated and provider agrees to undertake or undertakes such diagnosis/evaluation/treatment (§2.11)

• The final 2017 rule requires that, upon request, patients who have included a general designation in the “To Whom” section of the consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures)

• If no treating provider relationship, name of third-party payer or name of entity or individual participants with treating provider relationship or general designation

• Can designate name of third-party payer (e.g., Medicare)

• Health Information Exchange + individual/entity or generally designated treating providers

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A Framework for Understanding Part 2-Consent

**TABLE 1—DESIGNATING INDIVIDUALS AND ORGANIZATIONS IN THE “TO WHOM” SECTION OF THE CONSENT FORM**

<table>
<thead>
<tr>
<th>40 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)(1)(B)</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)(2)(B)</td>
<td>Individual</td>
<td>No</td>
<td>Name of individual(s) (e.g., John Doe)</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(3)(B)</td>
<td>Entity</td>
<td>Yes</td>
<td>Name of entity (e.g., Lakewood County Hospital)</td>
<td>None.</td>
</tr>
<tr>
<td>(a)(4)(B)(A)</td>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is a third-party payer as specified under §2.21(a)(4)(B)(A) (e.g., Medicare)</td>
<td>None.</td>
</tr>
</tbody>
</table>
| (a)(4)(B)(B) | Entity                                               | No                                                                              | Name of entity that is not covered by §2.31(a)(4)(B)(A) (e.g., HIE, or research institution) | 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., Lakewood 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). |
Why Did SAMSHA Revise 42 CFR Part 2?

• Last substantive updates prior to 2017/2018 were 30 years ago.
• Significant changes in health care delivery:
  • New models of integrated care that rely on information sharing to improve safety & outcomes
  • New focus on performance measurement & value based reimbursement
  • Evolving electronic infrastructure for managing and exchanging information and use of electronic health records
• Final 2017 rule: “SAMHSA has endeavored to strike an appropriate balance between the important privacy protections afforded patients with substance use disorders and the necessary exchange of information to improve treatment outcomes for these individuals.”

Regulation: 42 CFR Part 2 Revisions

Process of revising regulations started in 2014 with SAMHSA Part 2 Listening Session –
https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations

Notice of Proposed Rulemaking (81 Federal Register (FR) 6987)) - February 9, 2016 –
Regulation: 42 CFR Part 2 Revisions

• Updated final Part 2 rule: Jan. 18, 2017 (82 FR 6052).
  o Effective March 21, 2017
• Supplemental Notice of Proposed Rulemaking (SNPRM) concurrently published proposing additional changes (82 FR 5485)
• Final rule based on SNPRM completed Jan. 3, 2018 (83 FR 239)

Jan. 18, 2017, Final Rule (82 FR 6052)

Among the numerous changes made to the rule:
• Entire rule updated to apply to electronic as well as paper exchange of patient identifying information
• Definitions (§ 2.11) – revised/added several definitions, e.g., added “Treating provider relationship,” reference to ‘substance use disorder’ instead of alcohol abuse or drug abuse
• Applicability (§ 2.12) – Restrictions apply to information received from “Other lawful holders”
• Confidentiality restrictions and safeguards (§ 2.13) – added List of Disclosures requirement
Jan. 18, 2017, Final Rule (82 FR 6052)

- Consent requirements (§ 2.31) – e.g., permits a general designation in the “To Whom” section of the consent
- Medical emergencies (§ 2.51) – Revised consistent with statutory language
- Research (§ 2.52) – E.g., more closely aligned with HIPAA and the Common Rule
- Audit and evaluation (§ 2.53) – Permits audits and evaluations to meet certain CMS requirements

Jan. 3, 2018: Final Rule (Based on 2017 SNPRM)

EFFECTIVE FEBRUARY 2, 2018

Confidentiality of Substance Use Disorder Patient Records

A Rule by the Health and Human Services Department on 01/03/2018

Jan. 3, 2018: Final Rule (Based on 2017 SNPRM)

- Permit additional disclosures of patient identifying information by lawful holders to contractors, subcontractors and legal representatives with initial patient consent, to facilitate payment and healthcare operations such as claims management, quality assessment, and patient safety activities. (Must include contract/subcontract provisions about Part 2).

- Permit additional disclosures of Part 2 patient identifying information by lawful holders to certain contractors, subcontractors, and legal representatives for the purpose of conducting an audit or evaluation

- Assist users of electronic health records (EHRs) by permitting use of an abbreviated notice of prohibition on re-disclosure more easily accommodated in EHR text fields.

Medical Privacy

- Part 2 currently aligns with HIPAA as feasible
- Substance use disorder patient records and information may be subject to HIPAA, part 2, and state laws
- Part 2 (§ 2.20) does not preempt more stringent state laws
- If both HIPAA and part 2 apply, follow the law that is more stringent
- 42 CFR § 2.20: If a disclosure permitted under the regulations in this part is prohibited under state law, neither the regulations in this part nor the authorizing statute may be construed to authorize any violation of that state law. However, no state law may either authorize or compel any disclosure prohibited by the regulations in part 2.
21st Century Cures Act

• SEC. 11002. CONFIDENTIALITY OF RECORDS.

• Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the "Secretary") first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

42 CFR Part 2 Listening Session, Jan. 31, 2018

See https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines for further information
Part 2 Listening Session, 2018

• 86 in-person participants at SAMHSA building in Rockville, MD, and roughly 1200 online (phone/Web conference). Comments accepted in-person, via phone and in writing to PrivacyRegulations@samhsa.hhs.gov through Feb. 28, 2018.

• Comments emphasized aligning Part 2 and HIPAA, further steps to foster care coordination and integrated care, need to respect stigma of SUD and impact on patients of privacy and confidentiality violations, need for more subregulatory guidance/technical assistance, electronic health records and consent implementation challenges.

• Sample comment: “Anything that you can do to better align Part 2 specifically with HIPAA is very much appreciated, and we urge administration to implement regulations that can bring us to that and really allow us to integrate care in the way that we would love to for the benefit of our patients.” -American Psychiatric Association

• Sample comment: “We specifically want to acknowledge the clarifications […] regarding the ability for lawful holders to disclose part 2 information with Medicaid agencies and other contracted managed care entities in the performance of Healthcare operations. We also wish to applaud the clarifications permitting part 2 data disclosures for Medicaid and shift audits and evaluations…. Those are positive changes to facilitate appropriate Medicaid oversight of the services that they provide. However, our members do remain concerned with the prohibition on disclosures for diagnosis, treatment, or referable treatment […] Medicaid agencies and their partners continue to pursue delivery system and payment reforms to promote coordinated and integrated care across all healthcare needs.” -National Association of Medicaid Directors.

SAMHSA Priorities

• In 2018, patient privacy remains a critical concern. However, equally important is the need for:
  • Providers to be able to share information to improve SUD patient treatment
  • SUD patients to benefit from integrated care
  • Patients, providers, and the overall health system to benefit from use of new technologies and approaches (e.g., Health Information Exchanges, Electronic Health Records, and Multi-payer Claims Databases)
  • Further consideration of the benefits of aligning Part 2 with HIPAA. See 2018 Final Rule: “SAMHSA plans to explore additional alignment with HIPAA and is considering additional rulemaking”
SAMHSA Priorities

Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, M.D., Ph.D.

“It is critical that we keep in mind that we aim to protect the rights of individuals with substance use disorders, their rights to privacy, but also the rights to high-quality care in a way no different than for others without substance use disorders seeking treatment. To do less under the assumption of a special need for privacy is itself discriminatory and assures those living with substance use disorders a lower standard of care. My personal view is that we reinforce stigma by making such delineations.”

-Comments at SAMHSA Jan. 31, 2018, Part 2 Listening Session

QUESTIONS OR COMMENTS?

THANK YOU!!!
Please contact us for assistance:
PrivacyRegulations@samhsa.hhs.gov

For Further Information: https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines
HIE User Tip:
Access to Recorded Webinars
April Salisbury
Director of Education & Training

Miss a webinar?
https://www.nmhic.org/events

Hyperlinks to recordings are coming soon!
Next month’s webinar

NMHIC and Population Health and Value Based Care
– Thomas East, PhD, CEO/CIO of NMHIC and LCF Research
May 15, 2018

Next Time

Not an HIE User yet?
Direct inquiries to Michelle Bowdich,
(505) 938-9909 or michelle@nmhic.org

Next date:
05/15/18, 11:30-12:30 pm