Advocacy Series, Session IV: Confidentiality Rule Changes and 42 CFR

Welcome, your facilitator will be:
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Advocacy Series, Session IV: Confidentiality Role Changes and 42 CFR

Wednesday, September 2, 2020 @ 3-4:30pm ET (JCT/MT/PT)

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- Asking Questions
- Handouts
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- Polling Questions

H. Westley Clark, MD, JD, MPH
- Dean’s Executive Professor of Public Health at Santa Clara University
- Former Director of the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services

NAADAC Webinar Presenter
CONFLICT OF INTEREST

I have no Conflicts of Interest to declare for this presentation
- H. Westley Clark

Objective

1. Discuss the 2020 Final Rule regarding 42 CFR Part 2
2. Describe the Changes to 42 USC 290dd-2(b) (if we have time)

Revised Rule Timeline

- SAMHSA Published NPRM regarding a revised 42 CFR Part 2
- Congress passes the CARES Act amending 42 USC 290dd-2(b)
- A Revised 42 CFR Part 2 took effect
- HHS has until March 27, 2021 to issue new regulations for 42 USC 290 dd
- Amended 42 USC 290dd takes effect

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42 CFR Part 2

- Federal regulations promulgated under the authority of 42 USC 290dd-2
- Has been in place since 1975
- Has undergone several modifications over the past years.
- Revised Rule effective August 14, 2020

42 CFR Part 2 Protects the Confidentiality of SUD Patient Records

- Continues to apply to federally assisted SUD treatment programs
- Continues to prohibit law enforcement's use of SUD records in criminal prosecutions against patients absent a court order
- Continues to restrict the disclosure of SUD treatment records without patient consent, except for:
  — Bona fide medical emergency
  — Scientific research, audit, or program evaluation
  — Appropriate court order

 Did not change the enforcement provisions

A Federally Assisted Program

- “Federally assisted” (defined at § 2.12 (b)) encompasses a broad set of activities, including management by a federal office or agency, receipt of any federal funding, or registration to dispense controlled substances related to the treatment of SUDs.
A Federally Assisted Program

- A “program” (defined at § 2.11) is an individual, entity (other than a general medical facility), or an identified unit in a general medical facility, that “holds itself out” as providing and provides diagnosis, treatment, or referral for treatment for a SUD.
  - Medical personnel or other staff in a general medical facility who are identified as providers whose primary function is to provide diagnosis, treatment, or referral for treatment for a SUD are also Programs.
  - “Holds itself out” means any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment.

Records – Revised Rule (§ 2.11)

- Records means 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) provided,
- however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider.

changed provisions

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Records – Revised Rule (§ 2.11)

“Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as records in the hands of the non-part 2 provider, but may be segregated by that provider. For the purpose of the regulations in this part, records include both paper and electronic records.”

Applicability and Re-Disclosure

- Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. [§ 2.12(d)(2)(ii)]
- Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2

Disclosures with patient consent
- Exceptions to the consent requirement
- Technical and practical guidance
Disclosures with patient consent

BASIC RULE

- Part 2 permits disclosures with a patient’s written consent
  - The consent form must include certain information, including:
    - Patient’s name
    - Information about the recipient and source
    - What kind of SUD information will be shared
    - Purpose of the disclosure

Consent Requirements

- An SUD patient may consent to disclosure of the patient’s Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.

Written Consent Requirements § 2.31

- Consent forms may now authorize disclosure to an individual or entity recipient
  - No longer required for entity to have a “treating provider relationship” with patient
  - Example of how to designate entity recipients:
    - Social Security Administration
    - Community Health Center
    - Local named hospital
    - Drug Court Team
    - Etc
Written Consent and Health Information Exchanges (HIEs) (§2.31)

Consent requirements largely unchanged for entities that facilitate the exchange of health data (e.g., HIE)
- However, you may now designate an entity participant in the HIE, even if the entity does not have a treating provider relationship

Verbal Disclosures to Primary Care (§ 2.11)

- Patient consent is required before sharing Part 2 records with providers outside the Part 2 Program
- If a patient consents, Part 2 program may verbally disclose protected information to a primary care provider (PCP)
- PCP may then enter the information received verbally into the patient record and that information loses its Part 2 protections
- Written Records provided to the PCP retain their Part 2 protections

Prohibition on Re-disclosure Notice (§2.32)

- Disclosures of Part 2 records must be accompanied by a prohibition on re-disclosure notice
  - Notice has a long and short version
  - Change
    - New language for the long version, § 2.32(a)(1)
    - Clarifies that prohibition on re-disclosure only applies to Part 2 records, not entire file
Disclosures Permitted w/ Written Consent

Disclosures for the purpose of “payment and health care operations” are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision.

SAMHSA

Disclosures Permitted w/ Written Consent (§ 2.33)

• When a patient authorizes disclosures for payment or healthcare operations, the recipient may re-disclose the records to contractors, subcontractors, and legal representatives to carry out the payment or healthcare operations
• The new regulations now contain an expanded, illustrative list of permissible activities

Example of Activities permitted by 42 CFR § 2.33(b)

<table>
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<tr>
<th>Activity</th>
<th>Description</th>
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<td>Fraud, waste and/or abuse</td>
<td>Review of care-medical necessity</td>
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<td>Medical review</td>
<td>Care coordination &amp; case management</td>
</tr>
<tr>
<td>Business management</td>
<td>Accreditation</td>
</tr>
</tbody>
</table>

Other payment/health care operations activities not expressly prohibited in this provision.
Disclosures to Central Registries and PDMPs

- Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.
- Subject to patient consent, OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.

State Central Registries (§2.34)

- OTPs may share and receive limited patient information in State Central Registries to prevent multiple enrollments (with patient consent)
- Now, non-OTP providers may also query the information in Central Registries in order to
  — Prevent multiple program enrollments
  — Prevent duplicative prescriptions
  — Inform prescriber decision-making regarding prescribing opioid medications or other prescribes substances
- Information still limited to medication and prescription

Prescription Drug Monitoring Programs (PDMPs) (New §2.36)

- A part 2 program or other lawful holder is permitted to report any SUD medication prescribed or dispensed by the part 2 program to the applicable state prescription drug monitoring program if required by applicable state law.
- A part 2 program or other lawful holder must obtain patient consent to a disclosure of records to a prescription drug monitoring program under §2.31 prior to reporting of such information.
Disclosures without Consent

- De-identified information
- Internal communication
- Medical emergency
- Qualified Service Organization (QSO)
- Reporting certain crimes
- Reporting suspected child abuse
- Research
- Audit and evaluation
- Court Order

Medical Emergency (§ 2.51)

- Basic Rule: Part 2 programs may share information with medical personnel to meet a bona fide medical emergency in which the patient’s prior informed consent cannot be obtained
  - Part 2 program must document the disclosure in the patient’s file
  - SAMHSA issued additional guidance earlier this year for using the medical emergency exception when providing telehealth services during COVID-19

Medical Emergencies (§ 2.51(a) (2))

Meet a bona fide medical emergency in which a part 2 program is closed and unable to provide services or obtain the prior written consent of the patient, during a temporary state of emergency declared by a state or federal authority as the result of a natural or major disaster, until such time that the part 2 program resumes operations.

- E.g., flood, hurricane, etc
Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).

Basic Rule: Part 2 programs and lawful holders may share data with entities regulated by HIPAA or the Common Rule.
- De-identified data recommended but not required.
- Revised Rule added:
  - Recipient may now be an entity subject to FDA regulations regarding protection of human subjects.
  - If part 2 program or lawful holder is a HIPAA covered entity, it may disclose data to any entity, so long as the disclosure complies with the HIPAA Privacy Rule [45 CFR § 164.512(i)].

Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.
Audit and Evaluation
(§ 2.53)

• Basic Rule: Part 2 programs and lawful holders may share patient records with certain entities conducting audits and evaluations
  — Entity conducting the audit must first agree in writing to follow Part 2 privacy and security
  — Information may only be used for the purpose of the audit/evaluation

Audit and Evaluation-Revised Rule
(§ 2.53)

Patient identifying information may now be shared with federal, state, or local government for audit or evaluation required by law
• Or government’s contractors, subcontractors, or legal representatives
• Patient identifying information may only be disclosed if audit or evaluation “cannot be carried out” with de-identified information

Audit and Evaluation-Revised Rule
(§ 2.53)

• Entities with direct administrative control over Part 2 programs may conduct audits and evaluations
• New Illustrative list of examples of audits and evaluations
Audit and Evaluation-Revised Rule

(§ 2.53)

(c) Activities included. Audits and evaluations under this section may include, but are not limited to:
(1) Activities undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to:
   (i) Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, to improve care and outcomes for patients with SUDs who are treated by part 2 programs;
   (ii) Ensure that resources are managed effectively to care for patients; or
   (iii) Determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD.
(2) Reviews of appropriateness of medical care, medical necessity, and utilization of services.

Undercover Agents and Informants

• Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.

Court Orders Authorizing Undercover Officers

(§ 2.67)

• Basic Rule: law enforcement may only place an undercover agent or informant in a Part 2 program (as employee/patient) with a court order issued with notice and for good cause — information obtained by agent may not be used to criminally investigate or prosecute a patient
• Revised Rule: court orders may now authorize placement of undercover agent/informant for up to 12 months from the date of placement, instead of 6 months.
Disposition of Records

• When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for “sanitizing” the device by deleting that message.

SAMHSA

Technical and Practical Guidance

Using Personal Devices: For employees, volunteers, and trainees at Part 2 programs
• Personal devices should generally not be used to communicate with patients
• However, if a patient contacts an employee (or volunteer/trainee) on their personal device, they should
  — Immediately delete the information from their personal account
  — Only respond via an authorized channel provided by the Part 2 program
DATA Segmentation
• For non-Part 2 programs that regularly receive Part 2 protected records, appropriate data processes are key
  — Records received from Part 2 programs should be segmented, separated, labelled or flagged in or to distinguish them from the general health record.

RESOURCES

• The Center of Excellence for Protected Health Information: https://www.coephi.org/resource-center
CARES ACT – EVEN MORE CHANGES COMING TO SUD CONFIDENTIALITY IN 2021

Coronavirus Aid, Relief, and Economic Security ("CARES") ACT and Substance Use Disorder Treatment Records

- The CARES Act removes longstanding privacy protections when information is shared for treatment, payment, and health care operations purposes, and weakens the prohibition against the use of protected records in criminal investigations and prosecutions.

- Unlike some prior legislative proposals, however, the new law retains two very important requirements of the original confidentiality law and regulations: (1) voluntary, written patient consent is still required before any initial disclosure of SUD records can be made for treatment, payment and health care operations purposes; and (2) patients who sign those consent forms still have the right to revoke their consent to prohibit future re-disclosures.

CONSENT

Currently
- Written patient consent required prior to sharing protected SUD information, including for purposes of treatment, payment or health care operations.
- That information also is prohibited from being re-disclosed by the recipient without patient consent, or in certain limited exceptions.
- The Health Insurance Portability and Accountability Act (HIPAA), on the other hand, allows information to be shared for treatment, payment, and health care operations purposes without the patient’s consent.
“Health Care Operations”

- Conducting quality assessment and improvement activities
- Reviewing the competence or qualifications of health care professionals, evaluating provider and health plan performance, training health care and non-health care professionals, accreditation, certification, licensing, or credentialing activities;
- Underwriting and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reimbursement of risk relating to health care claims.

“Health Care Operations”

- Conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs;
- Business planning and development, such as conducting cost-management and planning analyses related to managing and operating the entity; and
- Business management and general administrative activities, including those related to implementing and complying with the Privacy Rule and other Administrative Simplification Rules, customer service, resolution of internal grievances, sale or transfer of assets, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity. General Provisions at 45 CFR 164.506.

Consent under the new 42 USC § 290dd-2(b)

- Written patient consent is required before SUD records can be disclosed for treatment, payment and health care operations purposes, but once an initial consent is obtained, no additional consent is needed for disclosures for treatment, payment, and health care operations purposes.
- Information can be disclosed to any health care provider, even to those who do not have any treating provider relationship with the patient, and can be disclosed for functions that are not directly related to the provision of health care, such as fundraising on behalf of the health entity or provider, underwriting, legal services, training non-health care staff, and the sale or transfer of the health entity’s assets.
It shall be permissible for a patient’s prior written consent to be given once for all such future uses or disclosures for purposes of treatment, payment, and health care operations, until such time as the patient revokes such consent in writing.

Perpetual Consent

Right to Revoke

- Patients will retain the right to revoke their consent for future uses and disclosures of their SUD records, but information that has already been disclosed is no longer protected by the SUD confidentiality rule.
- Implication: After patient has given consent and has left treatment, the right to revoke is meaningless unless it is employed at the time of discharge.
- Issue: Will a patient recall that right to revoke before harm occurs?

Self-Pay Rule and 42 USC 290dd-2(b): Perpetuating Health Disparities

- While the CARES Act amendments to 42 USC 290dd-2(b) weaken patient privacy safeguards, they introduced the Self-Pay Rule to substance use treatment privacy.
- In short, a person who pays in full out-of-pocket can request that a substance use disorder treatment program not disclose information about their treatment to their insurer or for health care operations.

—From the CARES Act, “Section 13405(a) of the Health Information Technology and Clinical Health Act (42 U.S.C. 2799G(a)] shall apply to all disclosures pursuant to subsection (b)(1) of this section.”

42 USC 17935(a) and 45 CFR 164.522(a)(1)(ii)(A)
USE OF RECORDS

- Current law prohibits the use of SUD records in criminal proceedings against the patient unless authorized by a court order or by patient request.
- New law extends this prohibition to civil, criminal, administrative, or legislative proceedings conducted by any Federal, State or local authority:
  - Includes law enforcement investigations
  - Includes application for a warrant
  - Includes any proceeding before a Federal, State or local agency
  - Includes any criminal prosecution or civil action before a Federal or State court.

Anti-Discrimination Provisions

Currently, the SUD confidentiality law does not contain anti-discrimination protections.

Under the amendments, new anti-discrimination provisions will prohibit discrimination based on information in protected SUD records, no matter how the information was disclosed.

The anti-discrimination protections will extend to a broad range of federally funded settings, including: the admission, access to, or treatment for health care; employment; receipt of worker’s compensation; housing; access to federal, state, or local courts; or access to, approval of, or maintenance of social services and benefits provided or funded by federal, state, or local governments.

Disclosures of De-Identified Health Information to Public Health Authorities

Whether or not the patient gives written consent, the new law allows the content of such record may be disclosed:

‘‘(D) To a public health authority, so long as such content meets the standards established section 164.514(b) of title 45, Code of Federal Regulations (or successor regulations) for creating de-identified information.’’

- Implication: This section appears to permit public health authorities to require SUD programs to report patient specific information, as long as such authorities use that information for creating de-identified information.
Enforcement

- Currently, violations of the SUD confidentiality law are subject to criminal monetary penalties, but they are very rarely enforced; and there is no requirement to notify patients of a breach.
- Under the amendments, HIPAA’s civil penalties will apply, including the imposition of penalties for wrongful disclosure of protected information. The amendments will also extend HIPAA’s breach notification requirements to covered SUD providers (“Part 2 programs”) and to protected SUD records.

Breach Notification

- The new law imposes an breach notification administrative burden on SUD programs and other “covered” entities
- A covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information shall, in the case of a breach of such information that is discovered by the covered entity, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach

Definition of Breach

- Generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information.
- An impermissible use or disclosure of protected health information is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment.
- The Good Faith Exception to the definition of "breach": “the covered entity or business associate has a good faith belief that the unauthorized person to whom the impermissible disclosure was made, would not have been able to retain the information.”

https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html#:~:text=Definition%20of%20Breach,of%20the%20protected%20health%20information.&text=The%20extent%20to%20which%20the,information%20has%20been%20mitigated.
### Which HHS Agency will be in Charge of the New Rule

- Historically, SAMHSA promulgated changes to 42 CFR Part 2, while the Department of Justice was supposed to prosecute violations.
  - There is no evidence that the Department of Justice ever prosecuted violations of 42 CFR Part 2.
- Historically, the HHS Office of Civil Rights administered HIPAA.
- The New Law doesn’t specify which agency in HHS will be responsible.

### Common HIPAA Violations

- Snooping on Healthcare Records
- Failure to Perform an Organization-Wide Risk Analysis
- Failure to Manage Security Risks/Lack of a Risk Management Process
- Failure to Enter into a HIPAA-Compliant Business Associate Agreement
- Improper Disposal of PHI
- Insufficient ePHI Access Controls
- Failure to Use Encryption or an Equivalent Measure to Safeguard ePHI on Portable Devices
- Exceeding the 60-Day Deadline for Issuing Breach Notifications
- Impermissible Disclosures of Protected Health Information
- Denying Patients Access to Health Records

### 42 CFR §2.63 of 42 CFR Part 2 Court Orders

§ 2.63 Confidential communications.

(a) A court order under the regulations in this part may authorize disclosure of confidential communications made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment only if:

1. The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;
2. The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect;
3. The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.
On August 26, 2019, HHS/SAMHSA published a Notice of Proposed Rulemaking that would amend § 2.63(a)(2) by removing the phrase “allegedly committed by the patient” because it came to their attention that the erroneous addition of the phrase “allegedly committed by the patient” may hinder federal enforcement efforts targeted at rogue doctors and pill mills that had contributed to the opioid crisis.

Current regulation: The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect.

HHS/SAMHSA believed that it may be necessary for law enforcement to be able to get a court order to examine confidential communications of a part 2 program to investigate and prosecute, if warranted, individuals other than a patient who engage in drug trafficking related to the drug abuse crisis.

HHS/SAMHSA also believed these records may be necessary to establish that the part 2 program or an affiliated medical professional is trafficking drugs rather than providing appropriate treatment for substance abuse.

This proposed NPRM would not be affected by the provisions of CARES Act.

Thank You!

H. Westley Clark, MD, JD, MPH

hwestleyclark@yahoo.com
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- **September 9th, 2020**
  Social Media and Ethical Dilemmas for Social Media and Ethical Dilemmas for Social Media and Ethical Dilemmas for
  By: Samman Teklemariam, MA, LPC, OPM & Jessica O'Brien, MA, LCSW, CASAC, CPTM
  www.naadac.org/webinars

- **September 16th, 2020**
  Cognitive Restructuring for PTSD: Non-Exposure Treatment for Trauma
  By: Guy Langevin, LICSW, LADC I & Andrea Wolfe, MA, LCMHC

- **September 19th, 2020**
  Fostering Couple Recovery: Tools for Counselors and Therapists
  By: Robert J. Navarro, PsyD, LMFT, MAC

- **October 14th, 2020**
  Dying to Connect: Addiction as an Attachment Disorder
  By: Ellen E. Elliott, LCAS, LPC, CSAT, PhD Candidate

- **October 19th, 2020**
  Cultural Humility Series, Part VIII: Social Responsibility in the Addiction Profession
  By: Samman Teklemariam, MA, LPC, OPM & Jessica O'Brien, MA, LCSW, CASAC, CPTM

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  By: Anthony Pons, EdD, LCSW, MAC, SAP and Mia Pons, EdD, LPCC, MAC

• Part III: Do You Know Who You Are and For Whom You Provide Services?
  By: Jordan Bernabeau, PhD

• Part IV: Critical Issues in LGBTQIA Patient Care
  By: Arturo V. Infante, PhD, LCSW, MAC and Peter Pomeroy, LPC, NCC

• Part V: Substance Use Disorder Treatment for Latvia Communities
  By: Partick Nelson, PhD, MAC, NCAC II

• Part VI: Why Do Matters Now More Than Ever
  By: R. Booth, PhD

• Part VII: Four Directions of Diversity: Honoring Differences
  By: Don Glos, Mohican Nation

• Part VIII: Social Responsibility in the Addiction Profession
  By: Genaro Galiobbi, CPC and Andrew A. Hill, LEPA, CASAC, CPTM

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Part Four: Stages of Clinical Supervision
By: Thomas Durham, PhD

Part Five: How to Sustain Clinical Supervision
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Seanna Tellman, MA, LPC, CPTM

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