Federal Substance Use Privacy Regulations: Past Time to Change!

16th Annual National Behavioral Health Information Management Conference

Eric Goplerud, Ph.D.
April 27, 2016
Vice President
Public Health Research
goplerud-eric@norc.org
301-634-9525

NORC at the UNIVERSITY of CHICAGO

42 U.S. Code § 290dd–2 - Confidentiality of records

- The Federal Statute behind 42 CFR part 2
- Short and Simple – only 730 words!
- ADAMHA Reorganization Act of 1992
  - Consolidates 1970 drug and 1972 alcohol laws
- Only 2 Requirements stricter than HIPAA
  - Patient Consent – "The content of any record…may be disclosed in accordance with the prior written consent of the patient
    - Medical emergency
    - Research
    - Court order
  - Prohibits use of patient information for criminal charges or investigation unless there is a substantial risk of death or bodily harm

42 C.F.R. Part 2 – Confidentiality of Alcohol and Drug Abuse Patient Records

- Meant to encourage people to seek out and remain in SA treatment without fear of prosecution by law enforcement and the government
- Promulgated 1975, updated 1980, 1983, 1987
- Creates a virtual shield against disclosure of PHI related to SA-related conditions and treatment
- Strictly prohibits disclosure and use of SA records of any federally assisted alcohol and drug use program *(federally assisted very broadly defined)*

42 CFR Part 2 is Much More restrictive than Federal Statute Requires

- Consent for a specific purpose
- Consent to a specific organization
- Consent must be time limited
- Consent is limited to minimum necessary for the specific purpose
- Highly formalized content
- Prohibits Re-disclosure

- **Civil penalties** for violations – fines (more on this later)

Part 2's "specific consent" requirements

- Name permitted to make disclosure
- Name to which disclosure is made
- Name of patient
- Purpose of disclosure
- How much and what kind of information
- Signature of patient
- Date of consent
- Statement that consent subject to revocation
- Date, event or condition consent will expire
- Information disclosed can not be redisclosed

Revising Part 2 – Federal Rule Making

- SAMHSA issued Proposed Rule amending 42 CFR Part 2 on Feb. 9, 2016
- Public had 60 days to comment—until **April 11, 2016**
- Agency considers comments received and then issues a Final Rule
- 385 comments received by SAMHSA
- Final Rule must be followed as part of the law

Legal Action Center summary follows

Proposed revisions - Consent

- New option for general designation in “to whom” section of consent form
  - Limited to those who have “treating provider relationship” with patient
  - Can include past, present, and/or future treating providers
- “From whom” section of consent form would now need to name specific individual/entity
- New patient right: Can request & receive list of individuals/entities to whom their info has been disclosed pursuant to a general designation consent

Proposed revision -- research

- Changes make it more consistent with HIPAA research requirements (e.g., Institutional Review Board)
- Maintains core protections of 42 CFR Part 2 (including prohibition on re-disclosure)
- Permit qualified researchers to access Federal secured Medicaid and Medicare database

Proposed revision – Qualified Service Organization

- Proposed Rule adds “population health management” to list of services QSOs can provide to SUD programs
- Cannot use Qualified Service Organization Agreement (QSOA) for “care coordination” (patient treatment component – should use consent)
- Can use QSOA for “medical staffing services” but not “medical services” (should get consent to make disclosures for treatment purposes)

Proposed revision – Medical Emergency

- Patient info can be disclosed w/o consent to medical personnel to meet a “bona fide medical emergency in which the patient’s prior consent cannot be obtained.”

- Previously could be disclosed w/o consent “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.”

Concerns from the Field with 42 CFR Part 2

- Low penalties
- “To whom” issues with consents
- No express discrimination provisions
- Setting sets the rules
- Redisclosure issues
- MH and SUD information are both categories of sensitive health information, yet not treated equally under the law
- No duty to warn provision
- Regulations contemplate written consent – we live in an increasingly electronic world

Disadvantages Persons with Substance Abuse Disorder

- Have to anticipate what care they will need from who in the future
- Must constantly update expiring consents
- Do not get extra attention and supports
  - That providers give to any patient with a known chronic disorder
  - That Health Care systems arrange for high risk and high utilized patient groups

Disadvantages Substance Use Treatment Providers

- Expense of constantly updating and re-doing consents
- Expense of EMR that can track and manage the complicated 42 CFR Part 2 consent requirements
- Public relations cost of being seen as non-responsive and obstructive by other Health care Providers

Keeps SUD Treatment System Small and Isolated

- General Health Care Providers
  - Less likely to add SUD treatment
  - Less likely to partner or do projects with SUD treatment providers
- Health Information Exchanges all say they will work out later how to manage 42 CFR part 2 and just exclude SUD treatment
- Excludes SUD providers and conditions from care coordination and care management initiatives

Increases Overdose Deaths

- Methadone is reported by the Centers for Disease Control and Prevention to be involved in 30 percent of prescription overdose deaths
- CDC also reports that the death rate from methadone overdoses was 6 times higher in 2009 than in 1999.
- While buprenorphine abuse and overdose deaths are much rarer, they are rapidly increasing in number.

Prescription Drug Abuse

- Prescription drug abuse in general has become a national epidemic.
- While individuals who have received specialized substance abuse treatment are less likely to abuse prescription medications than substance abusers who have not received treatment, they remain more likely to abuse prescription medications.
- Some persons who have received specialty substance abuse treatment relapse to prescription drug abuse and
- Some subsequently die of prescription drug overdoses.

False Promise of Magical IT Solutions and "Segmented Consent"

- IT vendors wanting new contracts say it's "do-able"
- Nobody has done yet
- IT Experts who are not vendors looking for contracts say "Sure, We can do anything….given enough time and money"
  - Who loves SUD treatment enough to give that money?
  - Who has put their initiatives on hold to give the SUD field time to catch up?
  - We will be Billions of dollars short and decades late
- Even if it gets built where are the staff to help patients continuously update their consents? Will Treatment providers re-contact all previous patients for every new regional project and annually to get new consents?

42 CFR Part 2 Makes SUD Patients and Providers Miss Out On

- The better Electronic Medical Records
- Health Information Exchanges
- Prescription Drug Monitoring and Improvement Systems
- Care Coordination
- Population Management

Substance use cannot be treated in isolation from health

- People with SUDs die 20+ years younger than their peers
- 100,000+ die annually,
  - 4th leading cause of preventable death in US.
  - Alcohol and drugs cause 1 in 10 deaths of working adults.
- Common BH and medical co-morbidities.
- Medically ill inpatients with SUDS at greatly increased risk of rapid rehospitalization, greater health care use, costs.
- SUD medical treatments, early intervention more effective
- Integrated care delivered in primary care, BH now standard of practice

Move from paper in 1970s to electrons in 21st Century

- Part 2 protects paper records in separate SUD tx programs from disclosure w/o patients' explicit consent.
- Paper stored onsite, physical secure in locked cabinets, shared by photocopy and mail.

- EHRs, HIEs, storage and exchange is much different.
- HIPAA , HIPAA regs, HITECH $$$ billions to incentivize EHRs and penalties if not meaningfully use EHRs.
- HIPAA, HITECH regulations create privacy and security standards EXCEPT for SUD records
- "big data" analytics EXCEPT SUD records

Concerns about the new regulations: Any program

42 U.S.C. 290 dd-2 applies to **"any program or activity"**, not to some uniquely defined and segregated set of substance use treatment programs that "hold themselves out to be"

*"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,* shall be confidential

What applying “Any” means

- Protects all SUD information from disclosure and use for criminal investigations or proceedings without patient consent extended to all, not just freestanding SUD tx
- Remove the barriers that prevent communication and coordination of care between treating health professionals.
- Remove peculiar QSOs, harmonizing with HIPAA and HITECH business associates.
- Entire health system required to protect patients’ substance use information

Ambiguous and sweeping definition of covered entity

- A psychiatric hospital or unit that provides substance use treatment to some of its patients
- Including “referral to treatment” sweeps every SBIRT program into the Part 2 restrictions.
- EAPs explicitly included
- OBOT providers
- Community BH providers licensed to tx substance use
- Treating cirrhosis, pancreatitis
- Parts of physicians’ records, such as their OBOT prescribing that is covered by Part 2, but not other parts
- Whole record of SUD tx programs including depression tx

Qualified Service Organizations are regulatory fictions

- By segregating certain providers as falling under Part 2, regulators must place special requirements on entities providing services to the Part 2 programs.
- Qualified Service Organizations, a unique creation that has no corresponding reference in 290 dd-2.
- Business Associate Agreements defined and regulated by HIPAA and HITECH are entirely serviceable, familiar
- Harmonize Part 2 with HIPAA adding requirements on BAAs to resist unauthorized disclosure of substance use information to criminal investigations and proceedings

Extension of protections beyond legislative authority:

- 290 dd-2 restricts disclosure IN CRIMINAL PROCEEDINGS (the bold letters are in the law)

"Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient."

- The proposed regulations expand this authority dramatically:

2.13(a) Part 2 data "may not otherwise be disclosed or used in any civil, criminal, administrative or legislative proceedings conducted by any Federal, state or local authority…"

No legislative authority for Part 2 penalties:

- The regulators propose to continue a set of penalties for infractions of Part 2 questionable enforcement authority.

  "Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18."

BUT -- No mention of privacy law violation fines, penalties, or offenses exist in Title 18.

- By contrast, violators of HIPAA privacy regulations are subject to hefty fines, revocation of professional and facility license or certification, and patients may sue violators for unauthorized disclosure under state laws.

Laughlin Steel Corp., 331 U.S. 416, 429 (1947); 67 C.J.S. Officers Sec. 3. The Attorney General may not provide legal representation solely to vindicate private rights or to redress private grievances in which the public has no vital interests. *Allen v. County School Board of Prince Edward County*, 28 F.R.D. 358 (E.D. Va. 1961). The Attorney General may, however, authorize a United States Attorney to represent a non-government party in a civil case where the interests of the United States are meaningfully involved. *See Brawer v. Horowitz*, 535 F.2d 830 (3d Cir. 1976); 28 U.S.C. § 517. *See also In re Debs*, 158 U.S. 564, 586 (1895). However, it is doubtful that cases involving attempts by law enforcement officers to obtain drug patient records could be said to involve Federal interests to such an extent as to warrant legal representation of alcohol or drug abuse program personnel by United States Attorneys or members of their legal staff. In short, United States Attorneys appear to have no obligation to act as legal representatives for program personnel when requests are made of such personnel by law enforcement officers for patient records or other patient information.

Unnecessary and ambiguous restrictions on use of substance use administrative data for research

- In response to criticism for redacting all SUD information in Medicaid, Medicare claims research data base from “big data” analysis
- Explicit permission to use Federal Medicaid, Medicare data in the research repository with appropriate IRB.

But

- All other administrative data sets, HIEs, ACOs, state Medicaid agencies, commercial insurance companies, Medicare Advantage plans, etc. not be able to make their data accessible to researchers

Recommendations for improvement

- **Any Program or Activity:** all substance use information protected from use in criminal justice investigations and proceedings.
- **QSOs:** Utilize the “any program or activity” language of the law and harmonize with BAA in HIPAA and HITECH.
- **Fines and penalties:** Move under HIPAA & HITECH; much stronger penalties.
- **Who information is disclosed to:** Harmonize with HIPAA and HITECH consents.
- **Research:** Allow research of additional administrative data sets with appropriate IRB.
- **EAPs:** Do not include Employee Assistance Programs as covered programs.

Integrate – separate is not equal

- Why should a person who has received SUD treatment not have the same right to make independent decisions regarding the nature, extent, and duration of disclosure as someone receiving any other health care service?

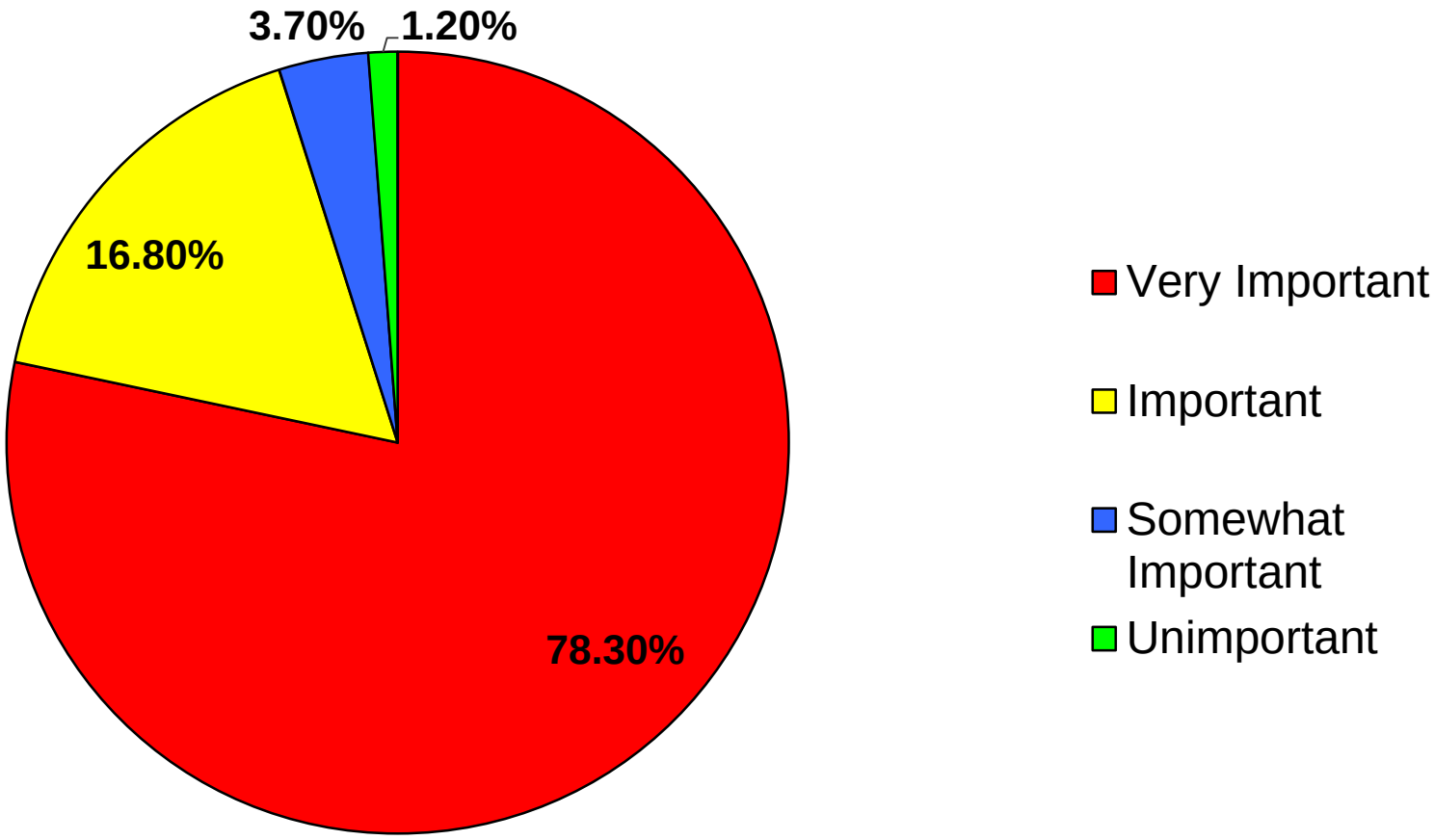
- Not allowing persons who have received SUD treatment to decide that they want their SUD treatment information shared in the same manner as all their other healthcare information is paternalistic, condescending, and discriminatory.

Time for Change

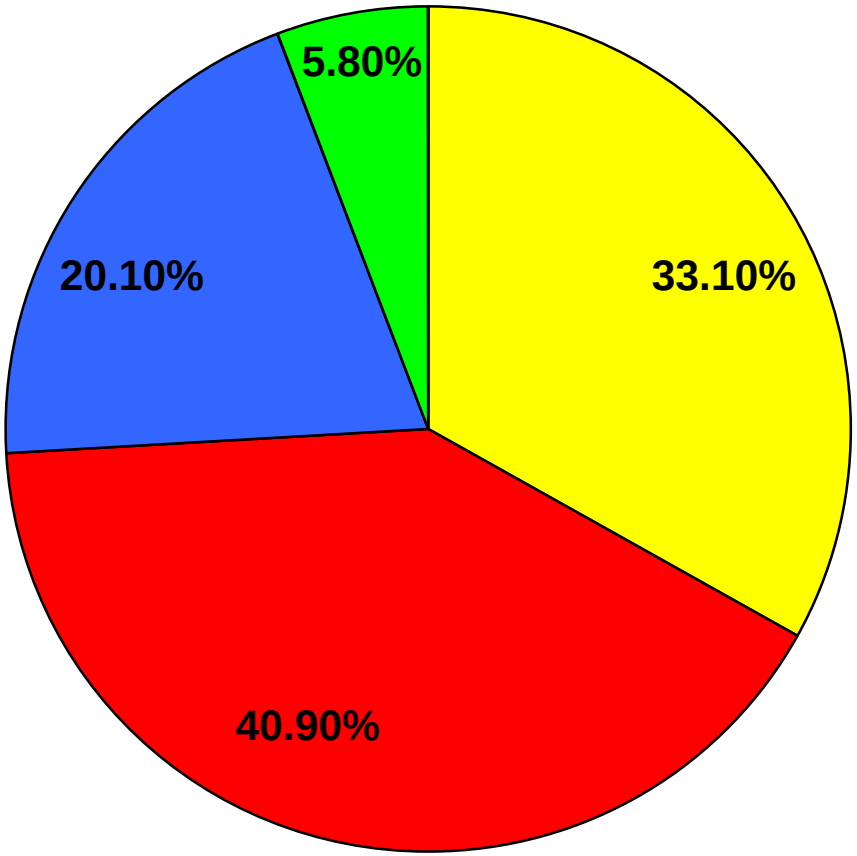
- **Best Option**
  - Repeal Federal Statute 42 U.S. Code § 290dd–2 - Confidentiality of records **except for prohibition on use for investigation or criminal charges**

- **Easier Option Revise 42 CFR Part 2**
  - As consistent with HIPAA as Statute allows
  - Applied as narrowly as Statute allows except **for prohibition on use for investigation or criminal charges**
  - Extend protections against use to all substance use records, regardless of the health care organization – ANY record

Integrated Care: How important do you think care coordination/integration of substance use, medical and mental health care is to improved outcomes for patients?

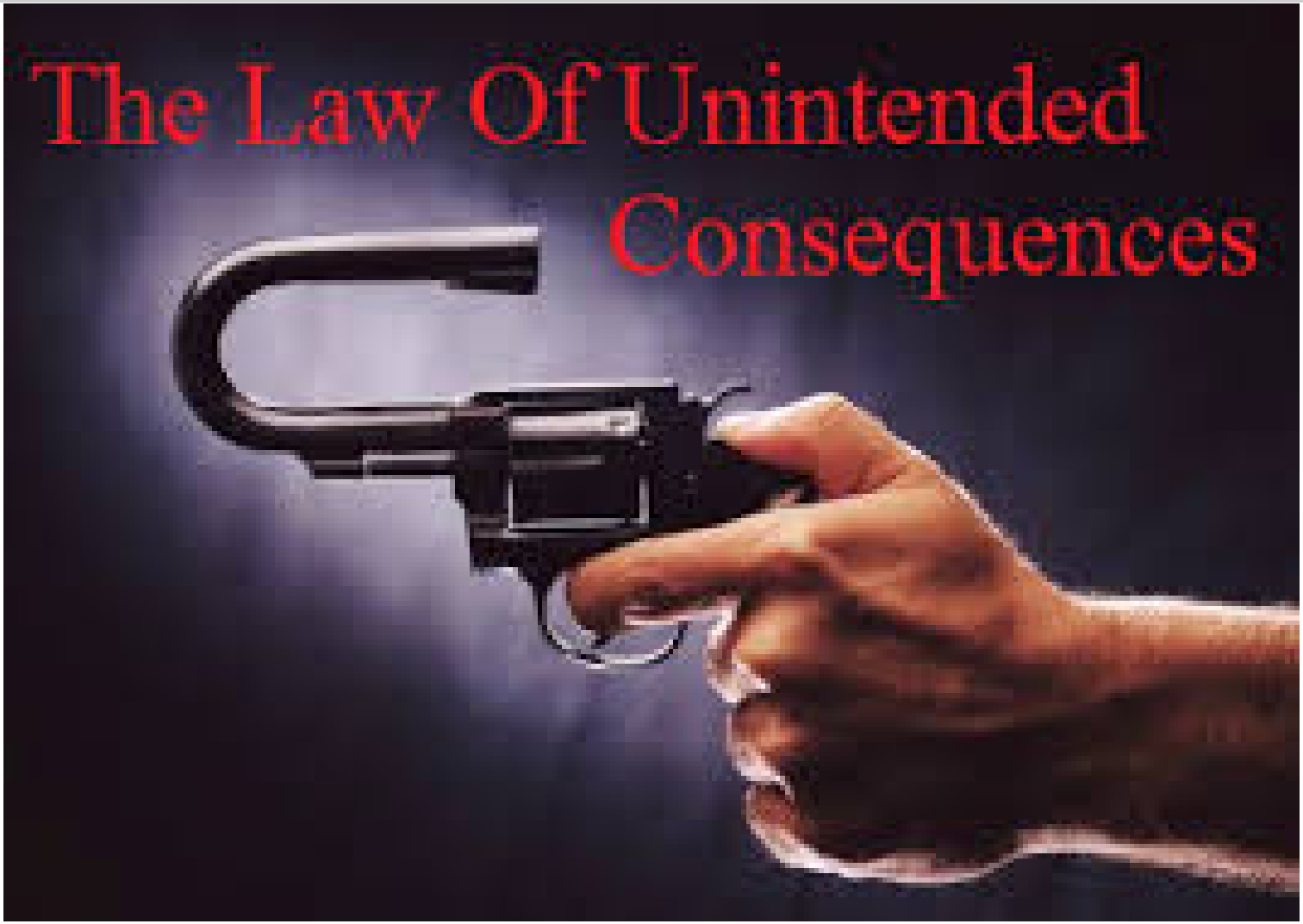


Revising Part 2 Regulations: What is your position on revising the regulations at 42 CFR Part 2?



- I am in favor of revising 42 CFR Part 2 to ease consent requirements in order to facilitate the sharing of SUD information among providers
- I am in favor of revising 42 CFR Part 2 to make it more consistent with HIPAA
- I am in favor of revising 42 CFR Part 2 to expand the protections to cover SUD information collected by all medical providers

August 13, 2013 Popovits/Vendome Webinar Poll Results


The Law Of Unintended
Consequences

Eric Goplerud Senior Vice President
Substance Abuse, Mental Health and Criminal Justice Studies
NORC at the University of Chicago
4350 East West Highway 8th Floor, Bethesda, MD 20814
goplerud-eric@norc.org | office 301-634-9525 | mobile 301-852-8427

Thank You!

NORC at the UNIVERSITY of CHICAGO

insight for informed decisions™