42 CFR PART 2: *Revised Rule 2020*

Enabling Collaboration and Improving Access

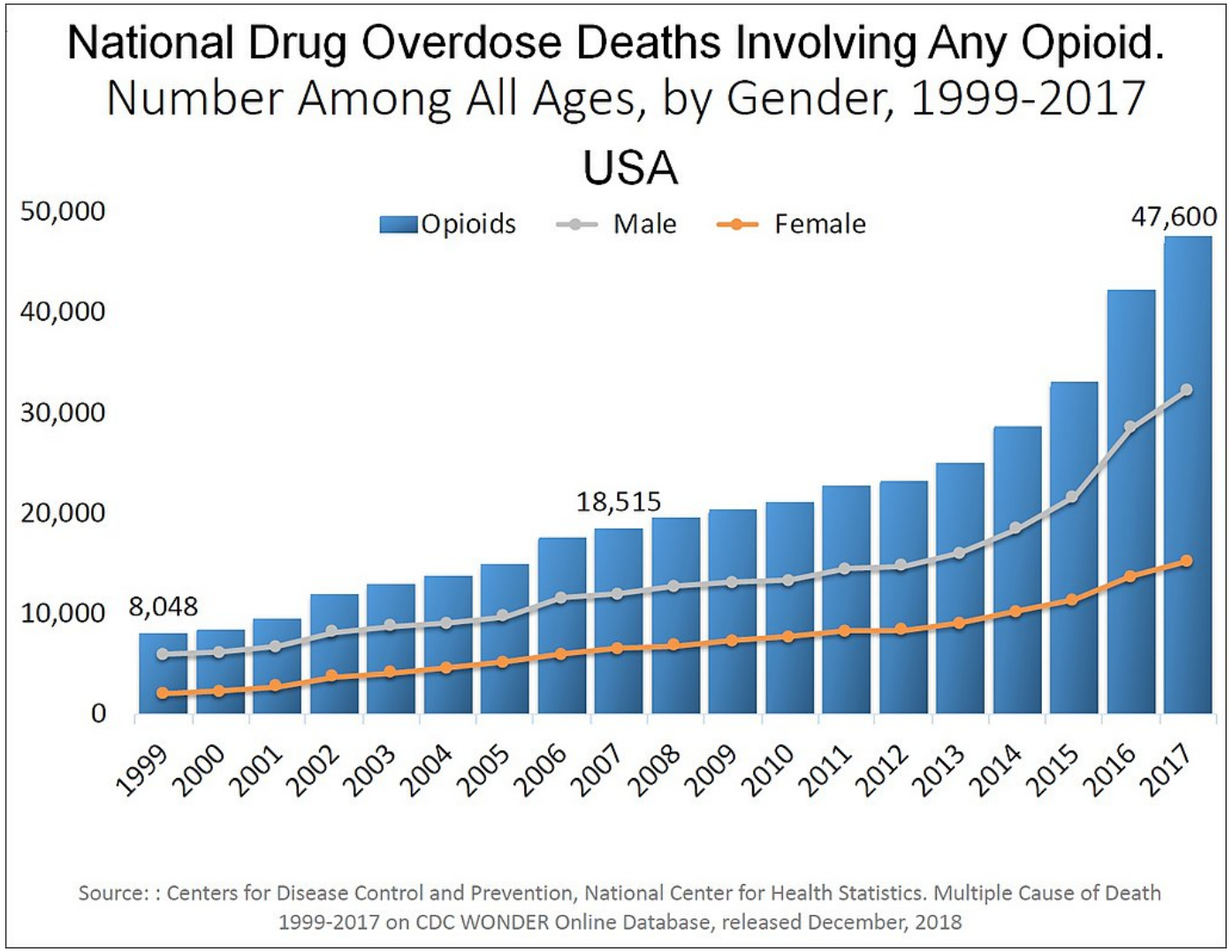
Peggy Gemperline RN, BSN, MBA

Executive Director

Recovery Works South Shore, KY

- **Learning Objectives:** At the conclusion of the Webinar, participants will be able to:
- Describe how the opioid epidemic changed the landscape of addiction treatment, creating a greater need for collaboration.
- Name 3 ways that 42 CFR Part 2 has not changed
- Identify 3 ways that providers will change their activities, as it applies to patient confidentiality and opioid treatment programs.

The Opioid Epidemic



Chronic Pain Management/Pill Mills

Dr. David Proctor

"Amid economic decline, doctors held the key to life strategies like worker's comp and SSI. Procter became the quickest doc around in preparing worker's comp papers."

"Dr. Proctor was well known in the area for prescribing amounts of pain pills to patients, with almost no diagnosis. First investigated by the Kentucky Board of Medical Licensure in 1988, He was investigated again ten years later, and the investigation revealed a corrupt man who extorted sex for pills and a waiting room that had become a corral for drug addicts. He served 12 years in prison and has since been deported back to his home country, Canada, where he resides today."

~Sam Quinones, Dreamland

The Opioid Epidemic and Drug Treatment

2010s: The Ohio Department of Health recognizes that the number of accidental overdose deaths exceeded traffic fatalities in certain Ohio communities. Within the next five years, this is a statistic recognized nationally

Legislation is passed that causes the closing of illegally operated “Pain Clinics,” creating demand for heroin. (2011)

2011: The Centers for Disease Control and Prevention (CDC) declares that overdoses due to pain killers reached epidemic levels. (2011)

Ohio Pill Mill Legislation in the Senate. https://nabp.pharmacy/newsroom/news/ohio-pill-mill-legislation-in-the-states-senate. Published May 19, 2011. Accessed Septemer 4, 2020.

Centers for Disease Control and Prevention Online Newsroom. Prescription painkiller overdoses at epidemic levels. Cdc.gov. https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html. Published November 1, 2011. Accessed March 28, 2019.

The Opioid Epidemic and Drug Treatment

- Opioid crisis resulted in an unprecedented spike in overdose deaths related to both prescription and illicit opioids
- Also resulted in correspondingly greater pressures on the SUD treatment system, and heightened demand for SUD treatment services.
- This crisis coincided with the rapid growth and development of electronic medical records

Drug Addiction Treatment Act of 2000 (DATA 2000)

- Part of the Children's Health Act of 2000, permits physicians who meet certain qualifications to treat opioid dependency with FDA approved narcotic medications, including buprenorphine, in treatment settings other than OTPs
- With input from SAMHSA, the Federation of State Medical Boards in 2013 adopted a revised version of the federation's office-based opioid treatment policies. The Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office provides model guidelines for use my state medical boards in regulating office-based opioid treatment
- Many state mental health/addiction treatment boards pushed for addiction treatment services to accompany MAT prescriptions that are covered by Medicaid.

Who Does 42 CFR Part 2 Apply to?

Part 2 applies to “federally assisted” substance abuse “programs.” The definition of “federal assistance” is broad: any entity that receives federal funding, is certified by Medicare, is registered to distribute controlled substances, or is a tax exempt non-profit considered to have received federal assistance.

To be a “substance abuse program, it must “hold itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment.”

Entities that provide some substance abuse services as part of a broader set of healthcare services is not necessarily covered under Part 2. A community mental health center that primarily treats mental health disorders, but addresses the substance abuse issues of some of their clients would not necessarily be considered a “Substance abuse program” under Part 2.

The Needs for Coordination and Collaboration Increase

- Part 2 providers experienced a higher administrative burden with increased need for communication and collaboration with non-Part 2 entities
  - Medical offices prescribing MAT products to their treatment clients
  - Greater numbers of clients with multiple needs, requiring communication with social service offices, such as Social Security, Health and Human Services to sign up for benefits, etc.
  - Greater numbers of clients referred to and from hospitals
  - Community Recovery Support entities, such as Peer Recovery Specialists
  - More FQHCs and community based healthcare services adding addiction screening tools and MAT services

42 CFR Part 2

- Confidentiality of Substance Use Disorder Patient Records regulations were originally issued to prevent access to patient records for the treatment of SUDs, in a time when there was not broader privacy and data security standard for health data, and persons with SUDs may encounter significant discrimination or experience other negative consequences if their information is improperly disclosed.
- In 2017 and 2018, SAMHSA published final rules, providing for greater flexibility in disclosing patient identifying information within the health care system, as well as providing clarity regarding healthcare operations and payment, while continuing to protect the confidentiality of substance use disorder patient records.

Summary of July 2020 Final Rule

- Revises the definition of "Records" to create an exception so that information communicated orally by a Part 2 program to a non-Part 2 provider for treatment purposes with consent does not become a "record" subject to Part 2 merely because it is reduced to writing by that non-Part 2 provider
- Proved that the recording of information about an SUD and its treatment by a non-Part 2 provider does not, by itself render a medical record subject to Part 2, provided that the non-Part 2 provider segregates any specific records that it receives.
- *This further clarifies that records created by non-Part 2 providers, based on their own patient encounters are* ***not covered by Part 2****. Segregation of a Part 2 patient record previously received can be used to ensure that new records created by non Part 2 providers will not be subject to Part 2.*
- *This* ***facilitates coordination of care activities by non-part 2 providers****, by alleviating fear of inadvertently violating Part 2.*

Summary of July 2020 Final Rule

- Permits patients to consent to the disclosure of their information for operations purposes to certain entities without naming a specific individual and includes special instructions for health information exchanges (HIEs) and research institutions.
- *Allows for release of information to agencies to assist patients with applying for benefits, coordinating care, without having to name a specific individual*
- Clarifies that non-Part 2 providers do not need to redact information in their or another non-Part 2 record and confirms that re-disclosure is permitted if expressly permitted by written consent of the patient or permitted under Part 2 regulations.

Summary of July 2020 Final Rule

- Allows disclosure to specified entities and individual for 18 types of payment and health care operational activities, including for care coordination and case management
- *This helps resolve lingering confusion under Part 2 about what activities count as "payment and health care operations." Further, the list has been expanded to include care coordination and case management activities. *this will affect how you structure your Part 2 compliant ROI form*
- Permits non-opioid treatment providers with a treating provider relationship to access central registries
- *This can help prevent dual enrollments, and also prevent patients enrolled in an OTP from accessing and diverting other opioid agonist/partial agonist MAT meds, in states that have central registries.*

Summary of July 2020 Final Rule

- Permits opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PMDPs), subject to patient consent*
- *This is meant to prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment. Very important to insure that consent is INFORMED, including informing the patient regarding who also has access to the PDMP*
- Authorizes disclosure of information to another Part 2 program or other SUD treatment provider during State or Federally-declared natural and major disasters
- Permits research disclosures of Part 2 data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule. Also now permits research disclosures to recipients who are covered by Food and Drug Administration

Summary of July 2020 Final Rule

- Clarifies that federal, state and local governmental agencies and third-party payors may conduct audits and evaluations to identify actions necessary to improve care; that audits and evaluations may include medical necessity and utilization reviews; and that auditors may include quality assurance organizations as well as entities with direct administrative control over a Part 2 program or a lawful holder. Also updates language related to quality improvement organizations (QIOs), and allows for patient identifying information to be disclosed to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluation required by law
- Amends the period for court-ordered placement of an undercover agent and informant within a Part 2 program to 12 months that starts when an undercover agent or informant is placed in the Part 2 program.

Summary of July 2020 Final Rule

What does NOT change?

- Does not alter the basic framework for confidentiality protection of substance use disorder (SUD) patient records created by federally assisted SUD Treatment programs.
- Part 2 continues to prohibit law enforcement's use of SUD patient records in criminal prosecutions, absent a court order.
- Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

Resources

1. Disclosure of Substance Abuse Patient Records – Does Part 2 Apply to Me?

   https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf

2. Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule

   https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html#

Peggy Gemperline BSN, RN, MBA

Executive Director

Recovery Works South Shore

4632 State Route 1043

South Shore, KY 41175

pgemperline@recoveryworksky.com