Compliance and Behavioral Health: What Practitioners Should Know Now

Christopher J. Shaughnessy

Gina M. Riddell, MPA-CHA, CHC

McBRAYER

Documentation

www.mmlk.com

McBRAYER

Behavioral Health in RHCs – SUD Treatment Documentation

If it isn't written down, it didn't happen.

McBRAYER

Behavioral Health in RHCs – SUD Treatment Documentation

- Both Kentucky and the federal government have separate recordkeeping requirements for substance use disorder treatments
- DEA requirements:
  - Buprenorphine treatment records should include a:
    - Patient Log which identifies patient by name or ID number
    - Name of drug prescribed or dispensed for the purposes of SUD treatment
    - Strength and quantity of the medication prescribed for the SUD treatment
    - Date of issuance of the prescription
      - This is best done by keeping a photocopy of the prescription with the patient's record
  - Records should be kept for 2 years
  - The DEA recommends keeping SUD treatment records separate, but it is not required

McBRAYER

Behavioral Health in RHCs – SUD Treatment Documentation

- Kentucky documentation requirements (201 KAR 9:260 and 270 and KBML Guidelines):
  - Appropriate medical history relevant to the medical complaint and past medical history
    - Including history of substance abuse or any prior treatment for substance abuse including psychosocial
  - Documentation of Physical Examination
  - Documentation of Treatment Plan
  - Obtain KASPER Report (for a 12-month period) and document in record accordingly
  - Document medical necessity to prescribe and dispense SUD treatment drugs
  - Patient consent to treatment
  - Clinic Policy regarding prescribing of controlled substances/SUD treatment medications
  - Controlled substance contract with patient

McBRAYER

Behavioral Health in RHCs – SUD Treatment Documentation (Continued)

- Specifically, 201 KAR 9:270 lists the following documentation requirements
  - The patient's history of present illness
  - Patient's history of substance abuse
  - Patient's social and family history
  - Patient's past medical and psychiatric histories
  - Physical examination of patient
  - Patient's injection use history which includes screening for HIV and hepatitis
  - Appropriate laboratory tests to include CBC, direct screen and a CMP
  - Obtain patient's consent and authorizations to obtain patient's prior medical records

Behavioral Health in RHCs – SUD Treatment Documentation (Continued)

- Documentation from treating physician regarding the review of patient's prior medical records and the treating physician's evaluation and treatment of the patient based upon those findings
  - If unable to obtain prior records, physician must document efforts in the patient's chart
- Documentation regarding obtaining and reviewing KASPER Report once every three months
  - Document any abnormal findings and discussions with patient
- Written explanation of treatment alternatives and risks involved with SUD treatment
- Obtain written Informed Consent from patient
- If patient is female of child bearing age and ability
  - Documentation of pregnancy tests and results
  - Documentation of counseling as to risk
  - Documentation verifying that patient is not currently breastfeeding

McBRAYER

Behavioral Health in RHCs – SUD Treatment Documentation (Continued)

- Document all in-office observations and/or presence of opioid withdrawal
- Document if patient is transferred from another treatment provider and has previously experienced withdrawal without a relapse
- Documentation regarding education to the patient about precipitated withdrawal

McBRAYER

Behavioral Health in RHCs-
Confidentiality of SUD Treatment Records

www.mmlk.com

McBRAYER

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Patient confidentiality regulations concerning ***substance use disorder*** ("SUD") are codified in the regs at 42 C.F.R. Part 2 ("Part 2")
- Applies to programs who are: (1) federally-assisted and (2) hold themselves out as providing alcohol or drug abuse diagnosis, treatment or referral for treatment
  - Federally assisted means: is licensed/certified/registered by the federal government, receives federal funds in any form, or is tax-exempt.

McBRAYER

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Prohibits disclosures of information (directly or indirectly) that identify a patient as having been diagnosed, treated, or referred for treatment of a SUD
  - Disclosures even apply when the person seeking patient information: already has it, has other ways to get it, has a subpoena/warrant (unless accompanied by a court order), or is authorized by state law
- There are only limited circumstances where patient information may be disclosed without patient consent. These confidentiality regulations are more stringent than HIPAA

McBRAYER

Disclosures of a Patient's Records – Substance Use Disorder

- **What information is protected**
  - Generally, substance use disorder information (including referral and intake) disclosed by patients who seek and receive treatment.
  - Includes, but is not limited to programs such as:
    - Treatment or rehab programs
    - EAP
    - Programs within a general hospital
    - School-based programs
    - Private practitioners who provide alcohol or drug abuse diagnosis, treatment or referral

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Part 2 differs from HIPAA:

Purpose of Disclosure	HIPAA Exception?	Part 2 Exception?
Emergency treatment	Yes	Yes
Non-emergency treatment	Yes	No
Payment	Yes	No
Health care operations (quality improvement, care management, etc.)	Yes, to other covered entities	No, only to qualified service organizations (outside services such as billing or legal help, provided there is an agreement in place)
Research	Yes, under certain conditions	Yes, under certain conditions
Subpoena	Yes, if patient notice or protective order	No. Requires court order

Does Part 2 Apply to Me?

From 42 CFR Part 2:
"An identified unit within a general medical facility is subject to part 2 if it **holds itself out** as providing, and provides, substance use disorder, diagnosis, treatment, or referral for treatment. In addition, **if the primary function** of medical personnel or other staff in a general medical facility is the provision of such services and they are identified as providing such services, they are considered a "Program" and, thus, subject to part 2."

From SAMHSA:
"Primary care providers **who do not work** in general medical care facilities meet Part 2's definition of a program if their **principal practice** consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, and they **hold themselves out** as providing the same. If their principal practice consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, but they do not hold themselves out as providing those services, then it is likely that they would not meet the definition of a program."

McBRAYER

Does Part 2 Apply to Me?

The phrase “holds itself out” is not defined in the regulations, but could mean a number of things, including but not limited to:

- State licensing procedures
- Advertising or the posting of notices in the offices
- Certifications in addiction medicine
- Listings in registries
- Internet statements
- Consultation activities for non-“program” practitioners
- Information presented to patients or their families
- or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment or referral for treatment.

Does Part 2 Apply to Me?

- SAMHSA's public advice on whether Part 2 applies is mixed and misleading at best.
- In reality, the best-case scenario is that Part 2 application is highly-specific, and there's no consistent one-size-fits-all application.
- Best practices: If you are dealing with substance use disorder in any way, consider yourself covered by Part 2.

Does Part 2 Apply to Me?

NOTE: There is a misperception that Part 2 only applies to opioid-related issues. This is false – it applies to most substance use disorders: alcohol use disorder, stimulant use disorder, etc. The regulation does exempt disorders of tobacco or caffeine use.

Disclosures of a Patient's Records – Substance Use Disorder

- Regulations prohibit the disclosure and use of a patient's records, unless the patient explicitly authorizes the disclosure, with few exceptions.
- Disclosures in most instances (even with an exception) is not explicitly required.
- Entities treating a substance abuse patient may contract and share information with a third party Qualified Service Organization

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Consent to disclose Part 2 information to different recipients for different purposes can be made on a single form, but that form must:
  1. Follow regulatory requirements of valid written consent, and
  2. Include a written prohibition on re-disclosure

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Elements of valid written consent under Part 2:
  - Specific name or general designation of the program or person permitted to make the disclosure
  - Name or title of individual or the name of the organization to which disclosure is to be made
  - Name of patient
  - Purpose of disclosure
  - How much and what kind of information is to be disclosed
  - Dated signature of patient or personal representative
  - Statement that consent is subject to revocation except to the extent already relied on
  - The date, event, or condition upon which the consent will expire

McBRAYER

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

- Disclosures must come with a warning:

"This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient."

McBRAYER

Disclosures of a Patient's Records – Substance Abuse

- Some things to remember:
  - A single Part II consent form can allow for the disclosure of patient information to different recipients for different purposes.
  - Part II does require a consent form to specify the kind and amount of information that can be disclosed to each of the recipients named.
  - Part II does allow for the disclosure of information under certain circumstances without consent of the patient during a medical emergency or in certain situations.
    - Examples – medical emergencies, child abuse reporting, crimes on program premises or against program personnel, court ordered disclosures.

Disclosures of a Patient's Records – Substance Abuse

42 C.F.R. Part 2 - Allowable "Disclosures"

- Written authorization/ Consent
- Qualified Service Organization
- Internal communication ("need to know")
- No patient-identifying information
- Medical emergency
- Audit/evaluation/ research
- Crimes (or threats of) on program premises or against program personnel
- Initial reports of suspected child abuse or neglect
- Court order meeting specifications

McBRAYER

Disclosures of a Patient's Records – Substance Abuse

When a patient doesn't consent and there is no life / health safety issue requiring disclosure without consent?

- Most often this occurs when there is a legal proceeding taking place.
- Occurs in either a civil (lawsuit, divorce, child custody) or a criminal (investigation or pending trial) matter.
- What to do when this happens.
  - Refer to the regulations which provide excellent guidance for how to proceed.
  - Lawyers will sometimes try to circumvent the rules.

Disclosures of a Patient's Records – Substance Abuse

Court ordered disclosures:

- Civil Cases
  - Party moving to obtain the records must obtain BOTH
    - a Court Order
    - a valid subpoena.
  - The Court is REQUIRED to include measures if the records are ordered to be produced to limit the disclosure of the patient's information.
- Criminal
  - Disclosure must be limited to law enforcement / prosecutors who are responsible for or are conducting the investigation or prosecution.
  - Must limit the use of the records to cases involving extremely serious crimes or suspected crimes.

<u>Remember - if you don't ensure disclosure is properly undertaken and ordered, you can be fined for an unauthorized disclosure.</u>

Behavioral Health in RHCs – SUD Treatment Confidentiality and Part 2

Key Takeaways:

- Purpose of Part 2: encourage treatment by protecting patients from the stigma attached with substance use disorders
- Applicability to providers:
  - If a patient sees a *primary care physician* for SUD treatment, those records might not be covered by Part 2, depending on if that physician is "federally assisted"
  - If a patient sees a *specialist* for SUD treatment, those records ARE covered
- Permissible disclosures: almost always requires informed consent
  - Informed consent: A patient's informed consent must be thorough enough to allow a continuum of care between the SUD providers and primary care in the RHC
  - Remember, even uploading electronically is a disclosure and impermissible without patient consent

McBRAYER

The New Stuff - EKRA

www.mmlk.com

McGUIREWOODS

Eliminating Kickbacks in Recovery Act ("EKRA")

- EKRA prohibits any solicitation or payment in exchange for patient referrals or to induce the referral of an individual to a recovery home, clinical treatment facility or laboratory.
- This federal law is an expansion of the kickback laws which will have a far-reaching effect on the healthcare industry – and in particular, laboratories.
- Unlike the federal Anti-Kickback Statute, EKRA applies to all healthcare benefit programs, including private payors.
- EKRA prohibits any person or entity from knowingly and willingly offering, paying, soliciting, or receiving, directly or indirectly, anything of value:
  - (1) in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
  - (2) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
  - (3) in exchange for an individual using a recovery home, clinical treatment facility, or laboratory's services.
- Violations of EKRA can result in criminal prosecution with fines of up to $200,000 and imprisonment for up to 10 years, or both.

Example of illegal activities

- **DALLAS** - Primex Clinical Laboratories, LLC has agreed to pay $3,500,000 to resolve allegations that it violated the False Claims Act by paying kickbacks in exchange for laboratory referrals for patient pharmacogenetic testing.
- In a related settlement, Mitch Edland, the Chief Executive Officer and owner of DNA Stat, LLC, has agreed to pay $270,000 to resolve similar allegations. Both settlements were announced by U.S. Attorney Erin Nealy Cox of the Northern District of Texas.

McBRAYER

- Arrangements between referring physicians and laboratories historically have been subject to abuse and were the topic of one of the OIG's earliest Special Fraud Alerts.

- Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business. – which would be considered a kickback.

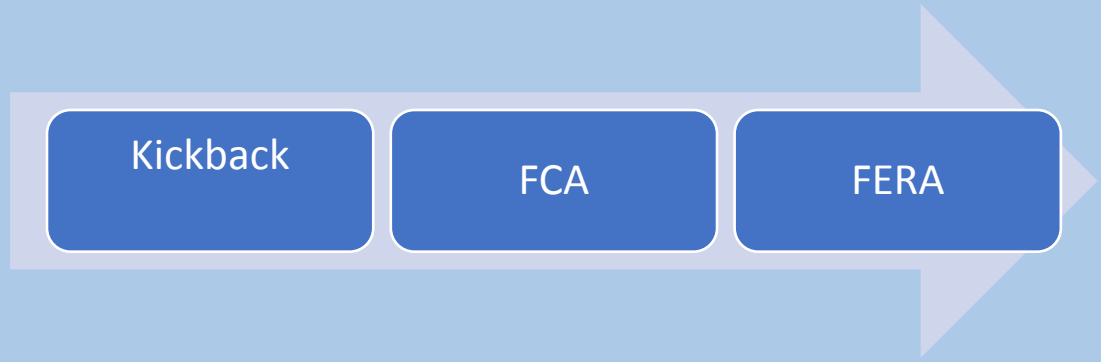
- When a laboratory pays a physician more than fair market value for the physician's services or for services the laboratory does not actually need or for which the physician is paid, this would also be considered a kickback.

- Arrangements in which laboratories provide free or below-market goods or services to physicians or make payments to physicians that are not commercially reasonable …this is also considered a kickback.

How does it tie together?

- Although physicians may order any tests they believe are appropriate to diagnose and treat their patients, Medicare will pay for laboratory tests only if they meet Medicare coverage criteria and are reasonable and necessary.

- When claims that include items or services resulting from a violation of the anti-kickback statute are not payable by Medicare and may constitute false claims under the False Claims Act, even if the items or services are medically necessary, which will also be a FERA violation!



McBRAYER

Any questions?

Christopher J. Shaughnessy
cshaughnessy@mcbrayerfirm.com
Gina M. Rawlins Riddell
griddell@mcbrayerfirm.com

(859) 231-8780
www.mcbrayerfirm.com

McBRAYER