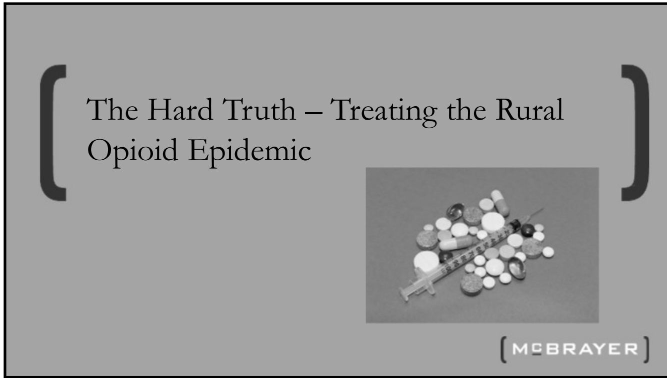

The Epidemic

Opioid-related overdoses (generally attributed to heroin and fentanyl) are continuing to rise across the nation. In 2015, more than 33,000 people died from opioid-related overdoses.

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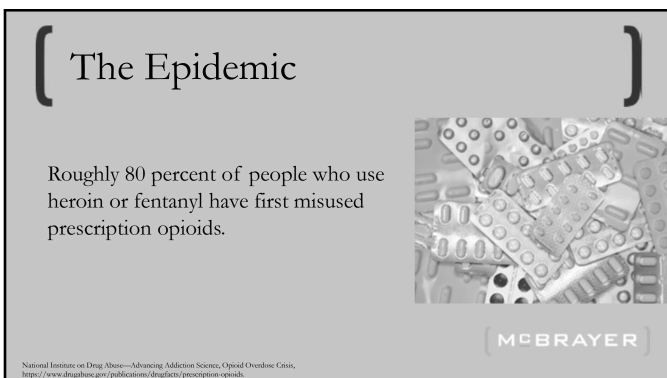
Centers for Disease Control and Prevention, Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016, https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm?s_cid=mm6712a1_w.



The Epidemic

The Appalachian Mountain Region accounts for 22% of the nation's opioid-related deaths between, despite representing only 20% of the US population in 2013.

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Appalachian Opiate Epidemic—Visualizing Overdoses, https://heroin.net/think/appalachian-opiate-epidemic/.

The Epidemic

- A study in 1999 noted that "at least 15 million rural residents struggle with significant substance dependence, mental illness, and medical-psychiatric comorbid conditions."
- Opioid use has seen a staggering change in 50 years, with a recent study showing that recent opioid users lived overwhelmingly in non-urban areas (75.2%) and were introduced to opioids through prescription drugs (75%).

Sources: Roberts, Battaglia, & Epstein, Frontier ethics: mental health needs and ethical dilemmas in rural communities, 1999
Cicero, Ellis, Surratt, & Kurtz, The changing face of heroin use in the United States: a retrospective analysis of the past 50 years

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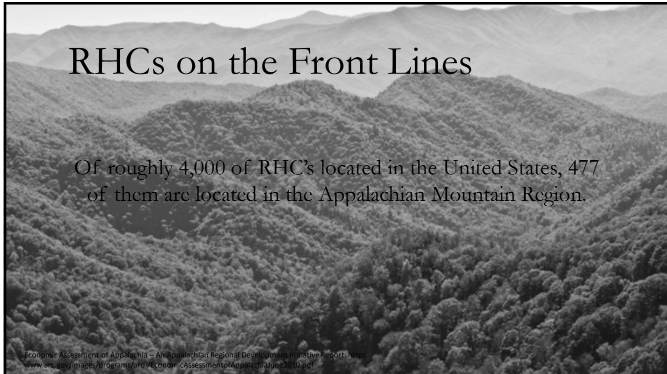

Three Ways RHCs Can Fight the Opioid Epidemic:

1. Adding Behavioral Health Services to Your RHC

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Behavioral Health in RHCs-The Basics

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Substance Use Disorder - Treatment

- Kentucky's approach to treating SUD has been a mixed bag
  - Suboxone – this opioid treatment drug is at the center of a storm of controversy
    - The Kentucky Board of Medical Licensure has established incredibly strict provisions for the prescribing of Suboxone to curb abuse of the therapy drug and to prevent doctor shopping, but this can lead to high compliance burdens that paradoxically drive providers away due to low reimbursement rates
  - To combat opioid abuse, Kentucky has been tightening regulations around prescribing physicians
    - HB 333 – designed to curb fentanyl abuse
      - Limits prescription of Schedule II drugs to a three-day supply if they are intended to treat acute pain
      - Schedule II drugs include oxycodone, hydrocodone and fentanyl

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Behavioral Health in RHCs – Basics

- 907 KAR 1:082 – Coverage Provisions and Requirements Regarding RHCs
  - Mental health disorders, substance use disorders and co-occurring mental health and substance use disorders are all covered services
  - Covered services also include (through various delineated practitioners):
    - Screenings and assessments
    - Psychological testing
    - Crisis intervention
    - Service planning
    - Individual, family, or group outpatient therapy
    - Many more services

Behavioral Health in RHCs – Basics

- Medicare Benefit Policy Manual:

  A RHC or FQHC visit is defined as a medically-necessary medical or ***mental health visit***, or a qualified preventive health visit. The visit must be a face-to-face (one-on-one) encounter between the patient and a physician, nurse practitioner, physicians assistant, certified nurse midwife, clinical psychologist or a clinical social worker during which time one or more RHC or FQHC services are rendered.

Integrating Behavioral Health – Benefits

- In addition to medical problems, a patient may have behavioral health issues contributing to the same or different issues. These problems can be identified and a comprehensive care plan can be coordinated using a team approach.
- Typically, primary care providers are not well versed in the diagnosis and treatment of behavioral health problems, thus the addition of the behavioral health provider provides an improved level of expertise.

Source for Integration of Behavioral Health in to RHC Practice slide content:
"Incorporating Behavioral Health Services in the Rural Health Clinic," National Organization of State Offices of Rural Health, 2016

Integrating Behavioral Health – Benefits

- Chapter 13 of the Medicare Benefits Policy Manual specifically states that medical and behavioral health providers may be reimbursed for services performed on the same day at the same location in the RHC. This generates revenue for the RHC and provides convenience and a more holistic experience for the patient.
- Patients have access to behavioral health services in a familiar environment without the stigma of visiting a practice specific to behavioral health.

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Integrating Behavioral Health

- A mental health visit is a medically-necessary face-to-face encounter between a RHC or FQHC patient and a RHC or FQHC practitioner during which time one or more RHC or FQHC mental health service is rendered
- Services furnished must be within the practitioner's state scope of practice
- Group mental health services do not meet the criteria for a one-one-one, face-to-face encounter in a FQHC or RHC

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Integrating Behavioral Health – Two Categories

Behavioral health services in the primary care setting fall into two broad categories:

I. The first category involves services designed to address the needs of patients with a specific behavioral health diagnosis.
   a) These services include
      1. psychiatric diagnoses and assessment;
      2. patient, family, and group psychotherapy;
      3. medication management;
      4. crisis psychotherapy;
      5. psychoanalysis; and
      6. transitional management services.
   b) These services are billed using psychiatric current procedural terminology (CPT) codes or evaluation and management codes. The specific code used will depend on the service provided and the credentials of the servicing provider.

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Integrating Behavioral Health – Two Categories

Behavioral health services in the primary care setting fall into two broad categories (cont'd):

I. The second behavioral health services category includes health and behavioral assessment and intervention (HBAI) services. HBAI services are services provided to patients not diagnosed with a psychiatric problem, but whose cognitive, emotional, social, or behavioral functioning affect prevention, treatment, or management of a physical health problem including chronic health issues (e.g., diabetes, obesity, or hypertension)
II. Examples of HBAI services include work with patients on issues related to medication compliance, diet, stress issues, smoking cessation, etc.

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Integrating Behavioral Health – Where to Begin

- Decide what your goals are and prioritize them
  - Expand access to mental health services?
  - Provide direct care vs. consultative services for PCPs
  - Improve primary care provider productivity?
  - Improve coordination of care?
- Determine the best ways to achieve each goal
  - Start simply and evolve with experience
  - Avoid competition for necessary resources

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Integrating Behavioral Health – Where to Begin

- Understand mental health reimbursement policies
  - Understand the mental health procedure and diagnostic codes and managed care systems (e.g., prior authorization, limitations on numbers of visits, paperwork requirements, etc.)
  - Recognize which types of providers are reimbursable by payers
- Focus on services that are reimbursable
- Understand different treatment models

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Behavioral Health in RHCs-
Change in Scope

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Integrating Behavioral Health – Change of Scope

- 907 KAR 1:055 – Section 10
  - An RHC can submit a change in scope request to DMS whenever it adds a covered service or increase in frequency of a covered service, or if there is a statutory/regulatory change that materially impacts the costs or visits of an RHC
  - The threshold is a that such a change in scope must result in a minimum of a 5% increase (or decrease) in the existing final PPS rate
  - **The bottom line is that the addition of behavioral health services to an RHC practice may result in an increased PPS rate**

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Integrating Behavioral Health – Change of Scope

- Change in scope documentation:
  - A narrative describing the change in scope;
  - A completed MAP 100501, Prospective Payment System Rate Adjustment, completed according to the Instructions for Completing the MAP 100501 Form; and
  - A signed letter requesting the change in scope.

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Behavioral Health in RHCs-
Substance Use Disorder Treatment

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Behavioral Health in RHCs – SUD Treatment Medication-Assisted Therapies

- One of the more highly-effective treatments of opioid abuse is the use of Medication-Assisted Therapies ("MATs") such as Suboxone
- Congress approved the Drug Addiction Treatment Act in 2000 to provide physicians more independence to prescribe buprenorphine to treat opioid addiction through a waiver process (DATA-waiver)
- Kentucky Board of Medical Licensure has issued strict regulations with regard to the prescribing of these substances
  - As mentioned earlier, these regulations tend to REDUCE the number of providers using MATs, as low reimbursement rates and high compliance burdens send providers to more lucrative locations or practice areas

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Behavioral Health in RHCs – SUD Treatment Medication-Assisted Therapies

- 201 KAR 9:270 requirements for Suboxone:
  - Physician must document extensive information about the patient and his or her medical history
  - Physician must perform certain tests, obtain KASPER reports, perform a physical exam, diagnose the patient to be in opioid withdrawal, educate the patient about the treatment, and obtain extensive consent to the treatment
  - After initial administration of the drug, the physician must then develop and implement a treatment plan of objective behavioral modification and a series of follow-up examinations at graduated intervals
  - Physician must make determinations on the continuation of treatment every three months and document medical necessity every twelve months

Behavioral Health in RHCs – SUD Treatment Medication-Assisted Therapies

- 201 KAR 9:270 requirements for Suboxone (cont'd):
  - Physician must obtain at least eight drug screens from the patient during the twelve months, and two must be random and include a pill count
  - At the end of the twelve-month interval, if the daily therapeutic dose exceeds the equivalent of sixteen milligrams of buprenorphine (Suboxone) per day and the physician is not board-certified in addiction medicine, the physician must refer the patient to another physician who IS certified by an addiction medicine board
- Not only are the KBML prescribing regulations tough, but pharmacists have discretion to refuse to fill the prescription
- Federal law limits the number of patients that may be treated this way - 30 in the first year, and a maximum of 100 thereafter

Behavioral Health in RHCs – SUD Treatment Medication-Assisted Therapies

- July 22, 2016 – President Obama signed the Comprehensive Addiction and Recovery Act ("CARA") into law
  - Expands access to substance abuse treatment services and overdose reversal medications by expanding federal privileges to prescribe buprenorphine to qualifying nurse practitioners ("NPs") and physician assistants ("PAs")until Oct. 1, 2021
  - NPs and PAs must complete 24 hours of training to be eligible for the waiver
  - In Kentucky, NPs are regulated by the Kentucky Board of Nursing, which is working to promulgate regulations on prescribing standards; these standards will likely be similar to the those enacted by the Kentucky Board of Medical Licensure

Three Ways RHCs Can Fight the Opioid Epidemic:

2. Learn, Train and Use Best Prescribing Practices

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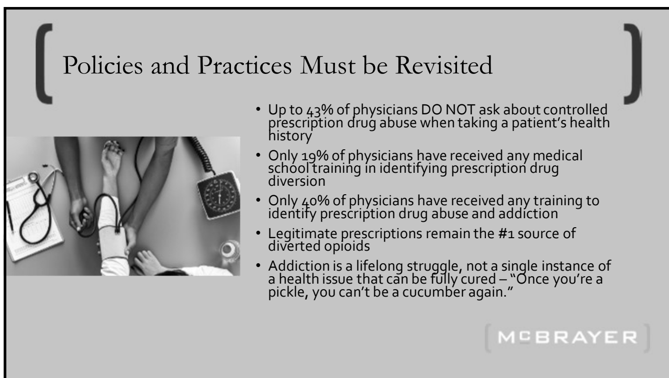
Policies and Practices Must be Revisited



- Up to 43% of physicians DO NOT ask about controlled prescription drug abuse when taking a patient's health history
- Only 19% of physicians have received any medical school training in identifying prescription drug diversion
- Only 40% of physicians have received any training to identify prescription drug abuse and addiction
- Legitimate prescriptions remain the #1 source of diverted opioids
- Addiction is a lifelong struggle, not a single instance of a health issue that can be fully cured – "Once you're a pickle, you can't be a cucumber again."

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Prescribing Controlled Prescription Drugs

- DO prescribe for legitimate medical reasons
- DO document history and physical examination
- DO screen for substance use disorder
- DO use proper prescription writing techniques
- DO use electronic prescriptions where possible

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Prescribing Controlled Prescription Drugs

- AVOID prescribing at intervals inconsistent with legitimate medical treatment
- AVOID prescribing large quantities of controlled prescription drugs
- AVOID issuing large numbers of prescriptions
- AVOID warning patients to fill prescriptions at different drug stores
- AVOID prescribing controlled prescription drugs when there is no relationship between the prescription and the condition being treated

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Three Ways RHCs Can Fight the Opioid Epidemic:

3. Litigate

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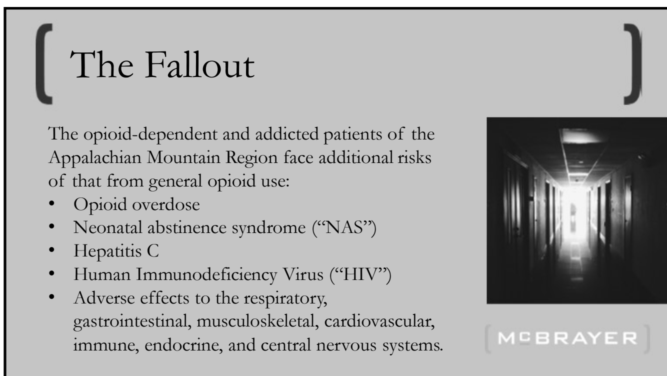

Neonatal Abstinence Syndrome (“NAS”)

- NAS is defined as the “sudden discontinuation of fetal exposure to substances that were used or abused by the mother during pregnancy
- NAS in the United States has more than quadrupled over the past fifteen years: one baby suffering from opiate withdrawal is born every twenty-five minutes.
- The number of pregnant women in Eastern Tennessee who abuse opioids is more than twice the national average.

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Neonatal Abstinence Syndrome, Prabhakar Kocherlakota, http://pediatrics.aappublications.org/content/134/2/e547.

Hepatitis C and Human Immunodeficiency Virus (“HIV”)

- A sudden increase in Hepatitis C and HIV is now corroborated with opioid abuse.
- In 2017, the Appalachian Mountain Region reported a larger number of new HIV cases compared to most other areas in the nation while Hepatitis C rates have tripled since 2010.
- Hepatitis C diagnoses among young women are rising ten times faster in rural Kentucky than nationally in recent years (with the proportion of babies born to infected moms surging to 1 in 63).

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http://theconversation.com/opioid-epidemic-causing-rise-in-hepatitis-c-infections-and-other-serious-illnesses-82040
https://www.courier-journal.com/story/life/wellness/health/2016/08/05/hepatitis-skyrockets-ky-women-drugs-blamed/87949710/

Adverse General Health

- The costs associated with treating these condition is huge. In fact, the Center for Disease Control and Prevention (“CDC”) estimates that the total “‘economic burden’ of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.”

- Since RHC’s are generally the most accessible facilities to these patients, they shoulder the burden of addressing each of these above-mentioned health implications.

- Since RHC’s are generally the most accessible facilities to these patients, they shoulder the burden of addressing each of these above-mentioned health implications.
  - It is estimated that RHC’s in the Appalachian Mountain Region collectively spend hundreds of millions of uncompensated dollars addressing the variety of health conditions that its opioid-dependent population suffers.
  - These uncompensated costs include but are not limited to: medically assisted therapies such as Suboxone; counseling services; increased compliance costs; diversion of assets from the provision of other needed healthcare; and denial of Medicaid/Medicare claims.

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https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

Uncompensated Costs

- MAT services in treating opioid-dependent or addicted patients.
- Counseling services
- Regulatory compliance costs
- Diversion of assets
- Denial of insurance claims

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Class Action Lawsuit

- On March 21, 2018, we filed Civil Action No. 6:18-cv-00087-GFVT in the United States District Court for the Eastern District of Kentucky, on behalf of multiple Rural Health Clinics operating within the Commonwealth of Kentucky;
- This is a class action lawsuit targeting the opioid producers we believe are responsible for the substantial burdens placed on rural health clinics;
- Since filing, the action has been transferred to the United States District Court for the Northern District of Ohio, so that it can be consolidated and litigated with a variety of other similar actions filed on behalf of other healthcare providers;
- Although the class has yet to be certified, class members will likely fall into one of three potential classes: All U.S. RHCs, all Appalachian-area RHCs, or all Kentucky RHCs.

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Class Action Lawsuit

- Why should my RHC participate as a member of this class?
  - Opioid manufacturers have been misleading physicians and healthcare entities about the risks of opioids for years, leading to the current crisis.
  - RHCs face staggering uncompensated costs from treating the epidemic, as well as diverted resources.
  - This lawsuit is to help RHCs recoup these costs, costs that are profits for opioid manufacturers.

Class Action Lawsuit

Where can I find out more?

- Visit http://www.RHCOpioidLawsuit.com.
- Speak with the McBrayer attorneys and representatives at our vendor table after this session and the rest of the day.

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Any questions?

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