

Opioid Crisis Training for Pharmacists

Data Regarding and Tools for Combating Opioid Misuse

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Goals for this Session

- Be able to identify populations that are the most likely to be impacted by opioid reliance and risk of overdose.
- Be able to formulate communications plan for discussing patients with prescribers.
- Know the purpose of KTRACS, how to register for use, what is in KTRACS, the purpose of delegates, and how to sign up for integration with electronic health records (EHRs) and pharmacy management systems (PMSs).
- Be able to educate their patients on proper storage and disposal of medications.
- Have a resource for identifying local behavioral health and substance use disorder providers.



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

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Opioid Use and Misuse

- There are a number of appropriate uses for opioids, including:
 - Treatment of moderate-to-severe pain
 - After surgery
 - After injury
 - Pain from conditions such as cancer
 - During hospice and palliative care



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Opioid Use and Misuse

- Risks of opioid use include:
 - Misuse
 - Addiction
 - Overdose
 - Death



Opioid Use and Misuse

RISE IN OPIOID OVERDOSE DEATHS IN AMERICA

A Multi-Layered Problem in Three Distinct Waves

351,000 people died from an opioid overdose (1999-2016)

The infographic consists of three diamond-shaped boxes representing different waves of opioid overdose deaths. The first box is black and labeled '1990s', indicating a rise in prescription opioid overdose deaths. The second box is orange and labeled '2010', indicating a rise in heroin overdose deaths. The third box is green and labeled '2013', indicating a rise in synthetic opioid overdose deaths. Below each box is an icon: a prescription pad for Rx Opioids, a syringe for Heroin, and a bag of pills for Synthetic Opioids. A CDC logo and a URL are at the bottom left.

- There have been three waves of opioid related deaths in the United States.
 - In the 1990s the first wave was the result of a dramatic increase in the number of opioid prescriptions for chronic pain.
 - In 2010 we saw the second wave as an increase in the use of illicit heroin drove a substantial number of new overdose deaths.
 - In 2013 we started to see the third wave of opioid related deaths, this time from the use of synthetic opioids, particularly fentanyl.

Rx OPIOIDS
Include natural, semi-synthetic, and methadone and can be prescribed by doctors

HEROIN
An illegal opioid

SYNTHETIC OPIOIDS
Such as fentanyl and tramadol are very powerful and can be illegally made

Learn more about the evolving opioid overdose crisis: www.cdc.gov/drugoverdose

OPIOID CRISIS TRAINING FOR PHARMACISTS

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Opioid Use and Misuse – US Data

- In 2017:
 - More than 191 million opioid prescriptions were written in the US
 - 58.7 prescriptions per 100 residents
 - Down from 81.3 in 2012
 - 17% of US Residents had at least one opioid prescription filled
 - 8.5% of all opioid prescriptions were for ≥ 90 MME, down from 15.9 in 2006
 - US average was 3.4 dispensed prescriptions per patient
 - Average number of days per prescription was 18 days up from 13 days in 2006

OPIOID CRISIS TRAINING FOR PHARMACISTS

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Opioid Use and Misuse – US Data

- Counties with high prescribing usually have:
 - Smaller cities or larger towns
 - Higher percentage of white residents
 - Higher number of dentists and primary care physicians per capita
 - More uninsured and unemployed
 - More residents with diabetes, arthritis, or a disability



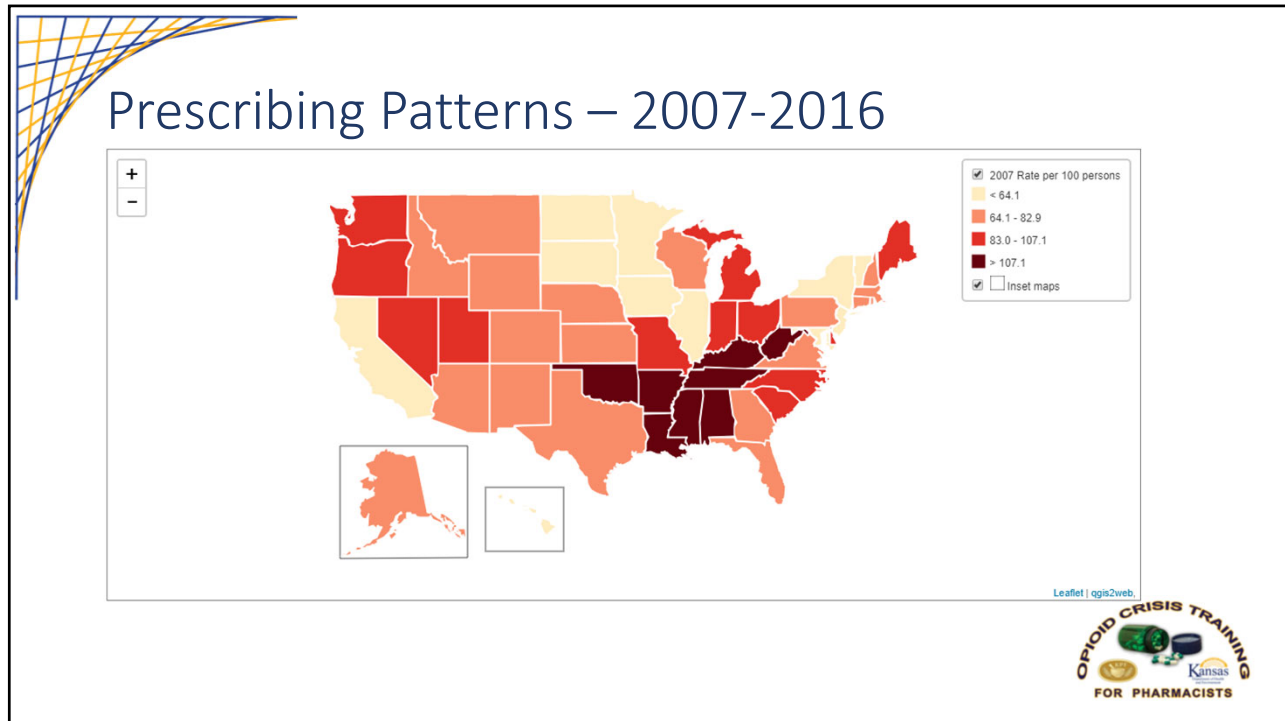
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Opioid Use and Misuse – US Data

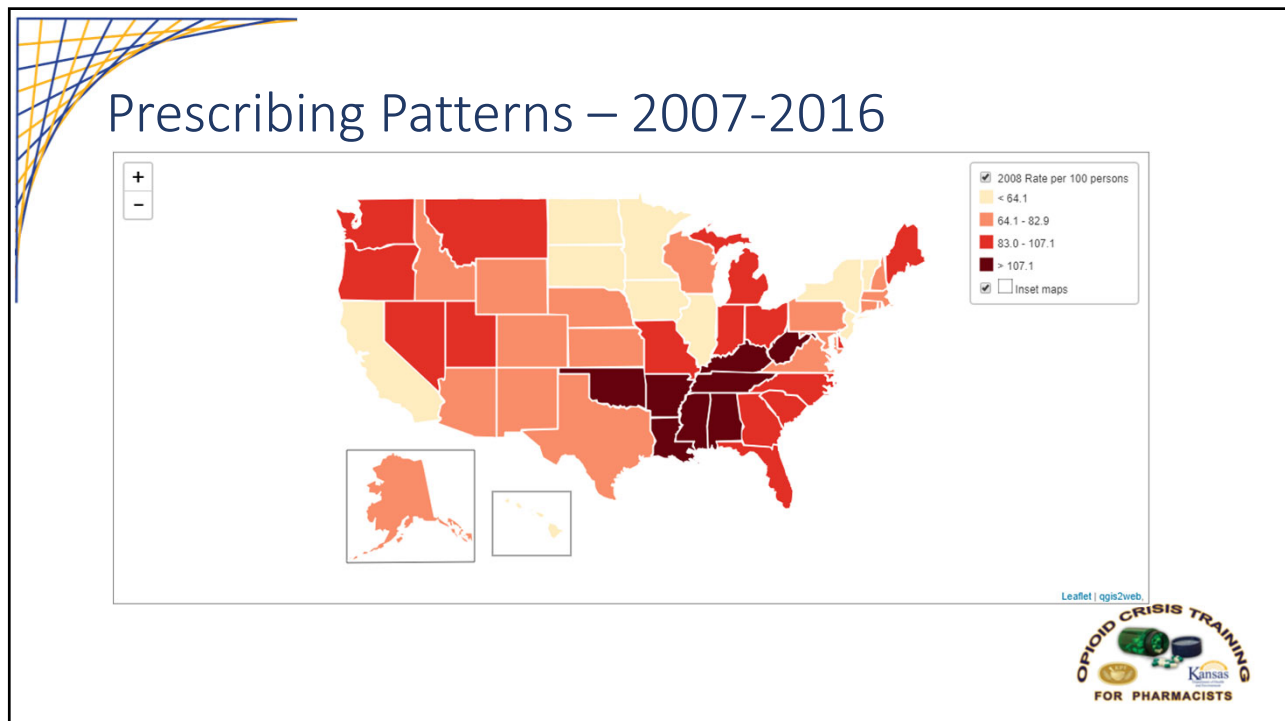
- What do we know about the crisis:
 - Approximately 25% of patients prescribed opioids misuse them
 - Approximately 10% develop an opioid use disorder
 - Roughly 5% who misuse transition to heroin
 - About 80% of people who use heroin, first misuse prescription opioids



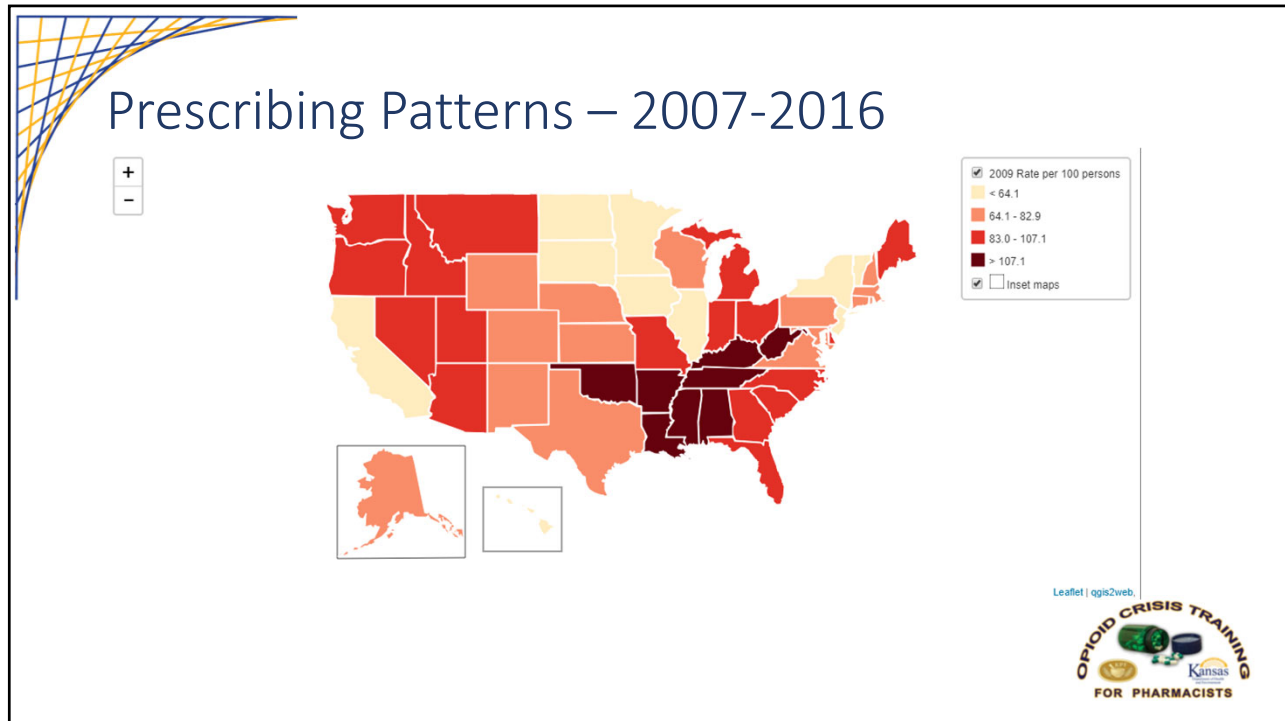
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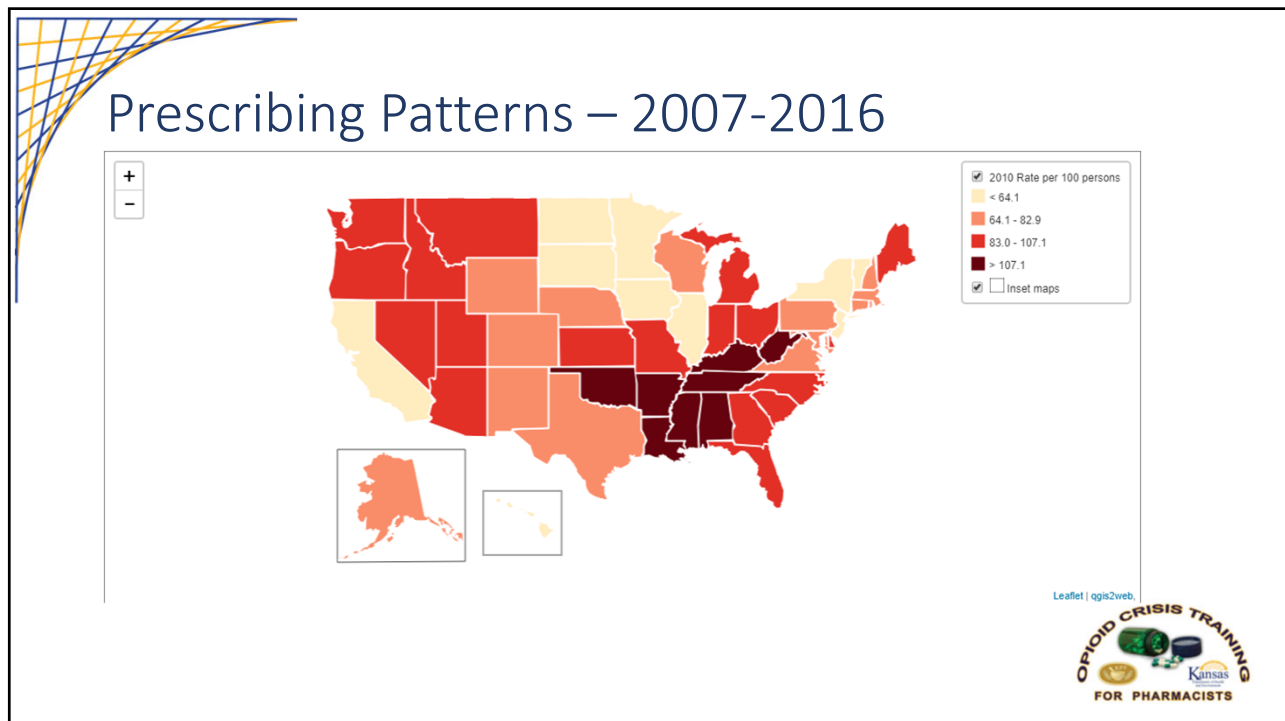
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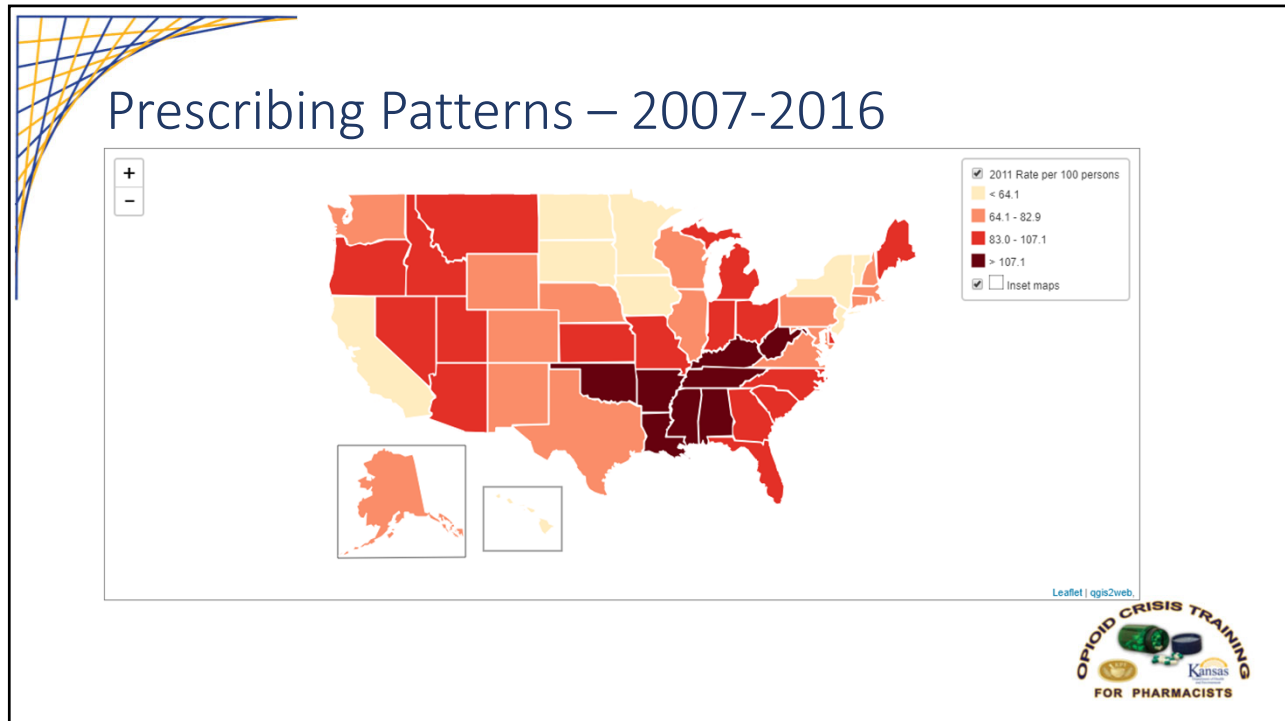
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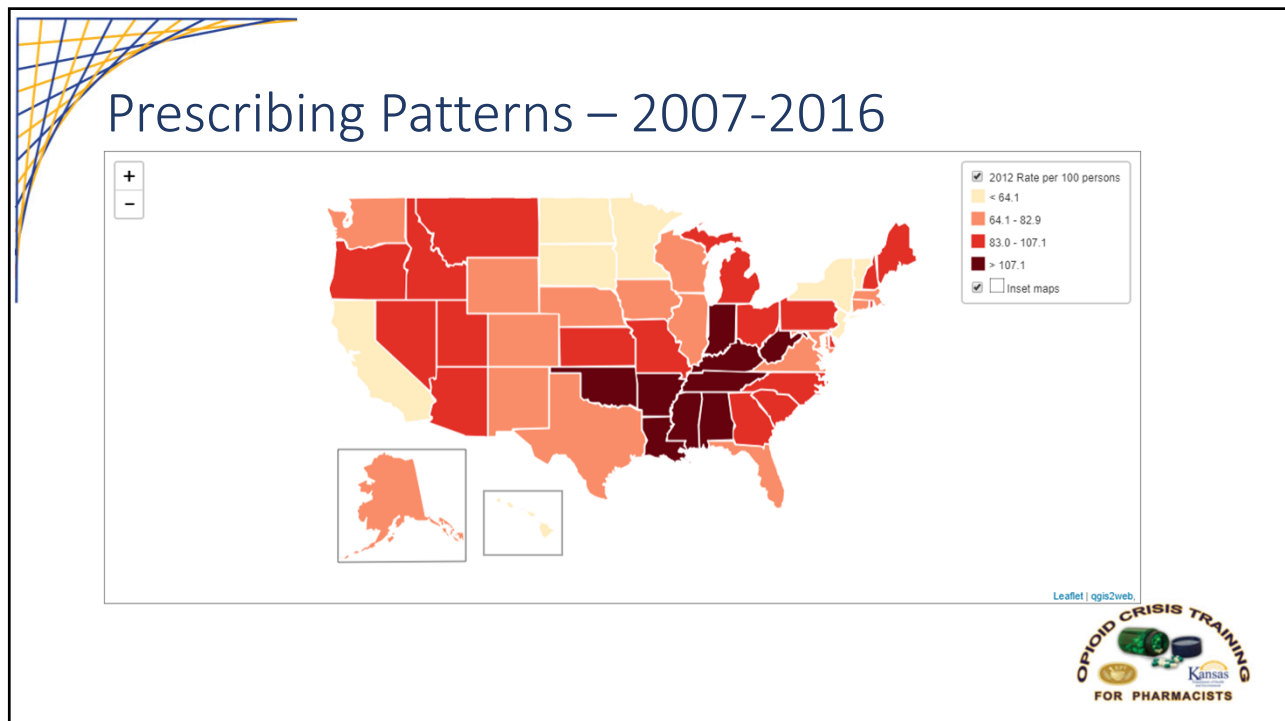
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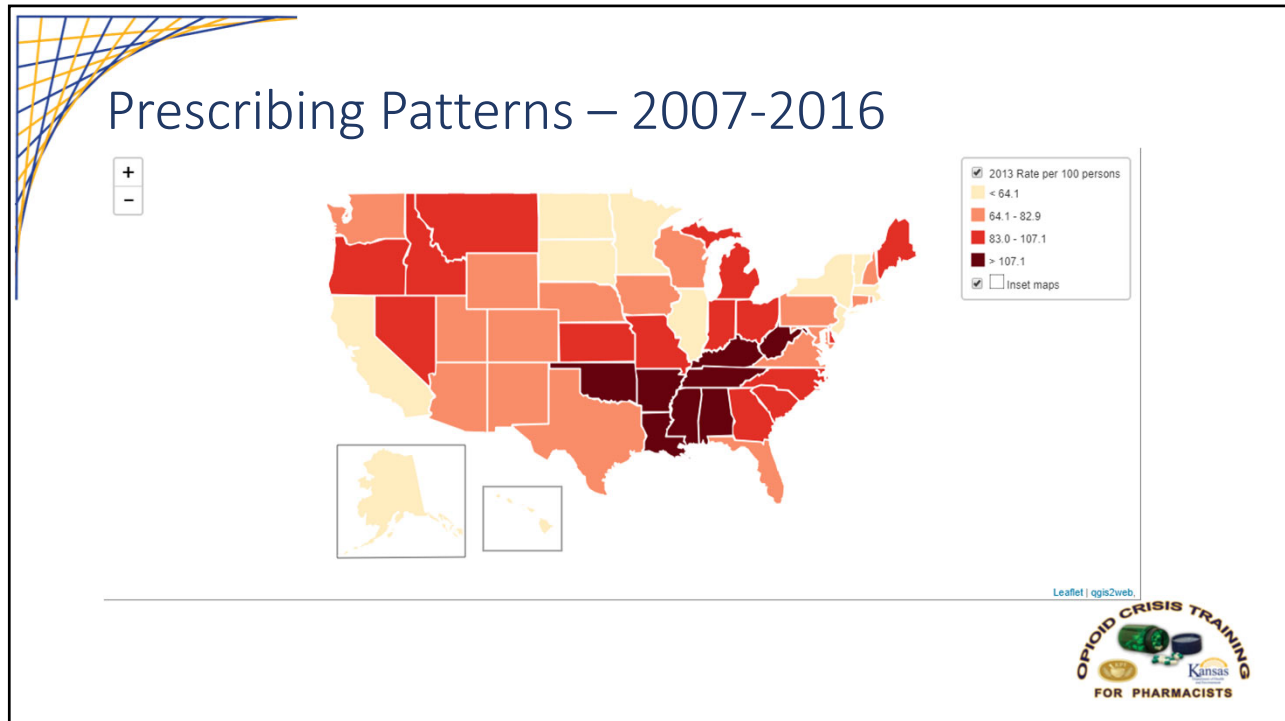
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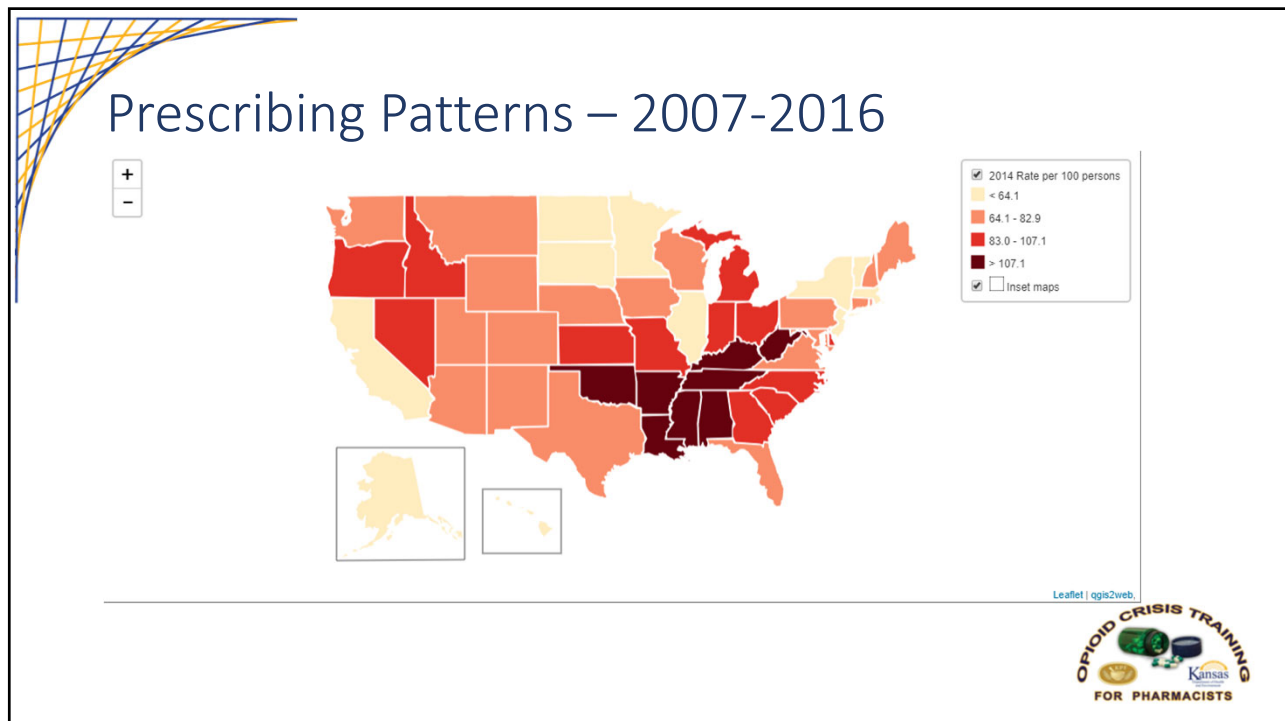
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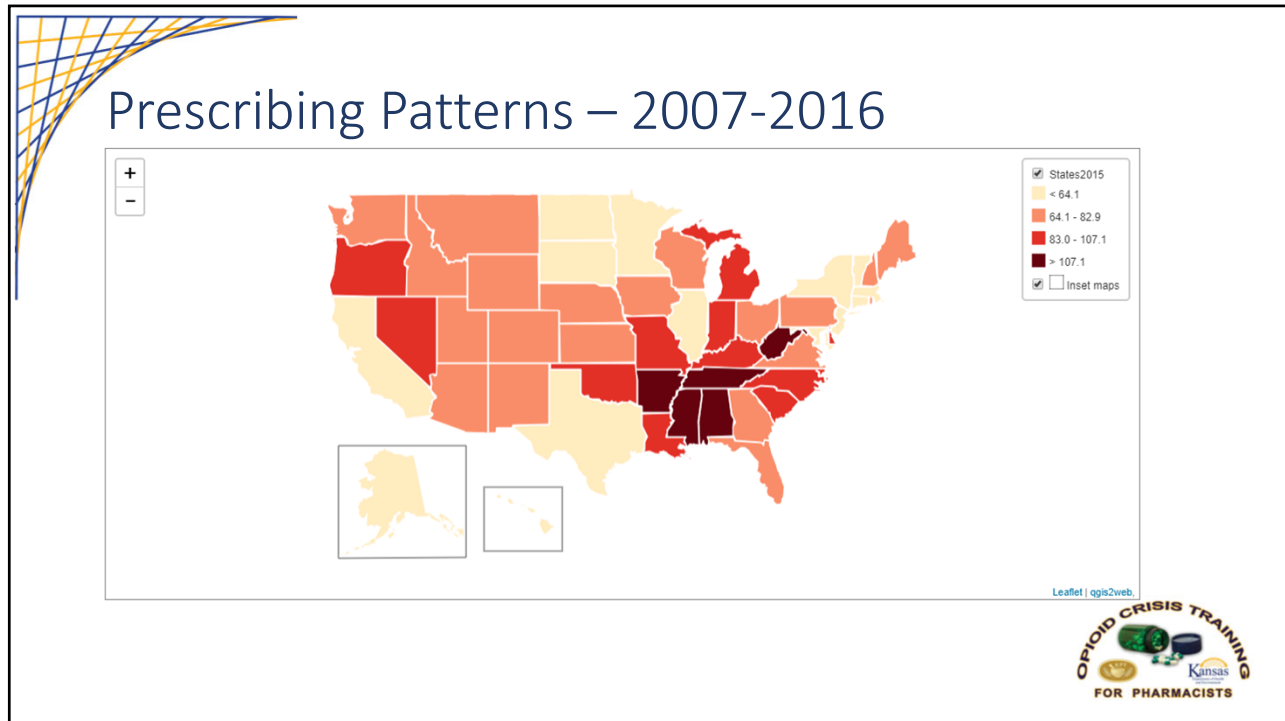
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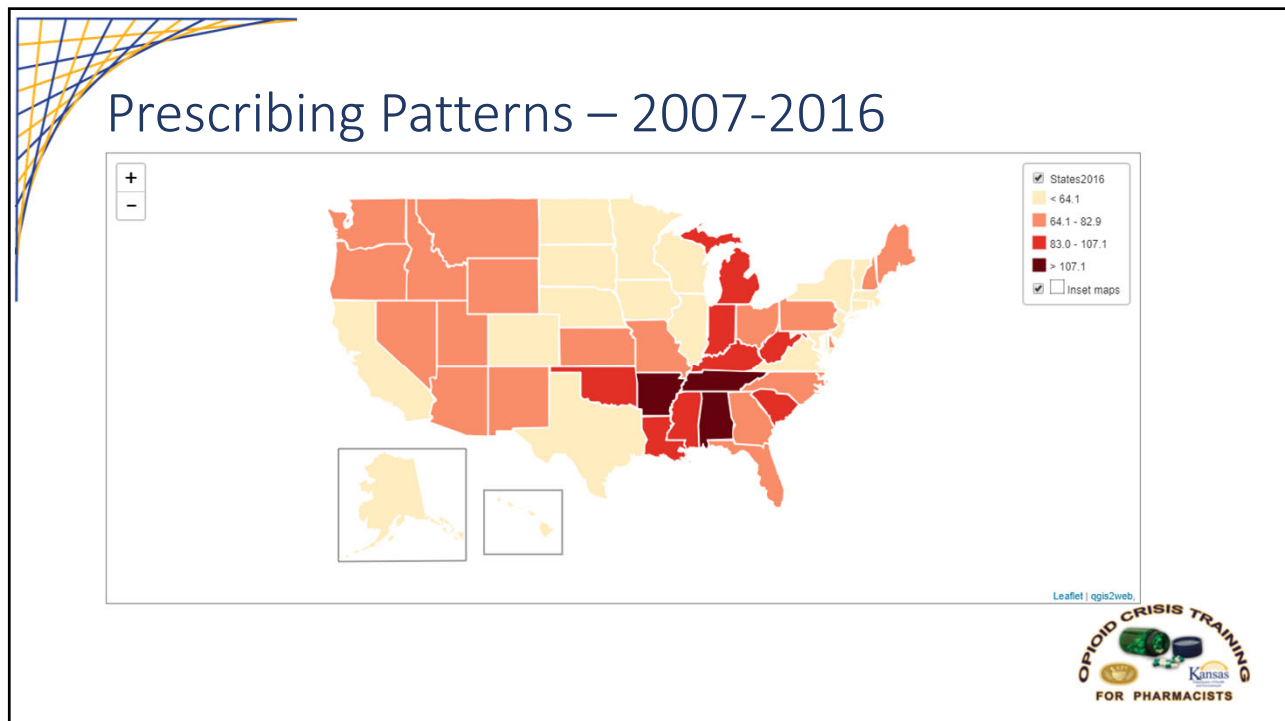
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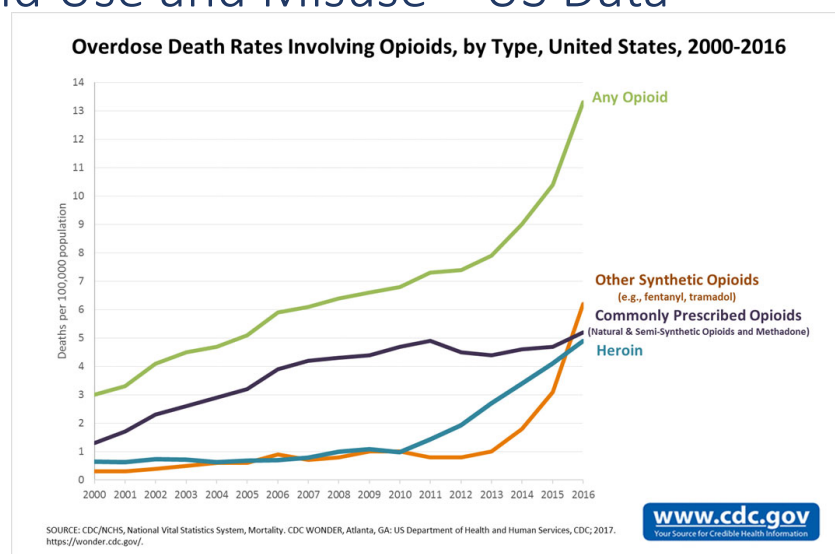
Opioid Use and Misuse – US Data

- In 2016:
 - The age-adjusted Death Rate for all drug poisonings rose from 11.9 per 100,000 population in 2007 to 19.8 in 2016
 - Even with the reduction in prescriptions, deaths from opioid overdose reached an all time high in 2016
 - 42,249 opioid related deaths
 - 17,087 deaths from prescription opioids
 - Highest death rates among those 25-54
 - The rate of overdose deaths from prescription opioids for men was 6.2 per 100,000 population, for women it was 4.3

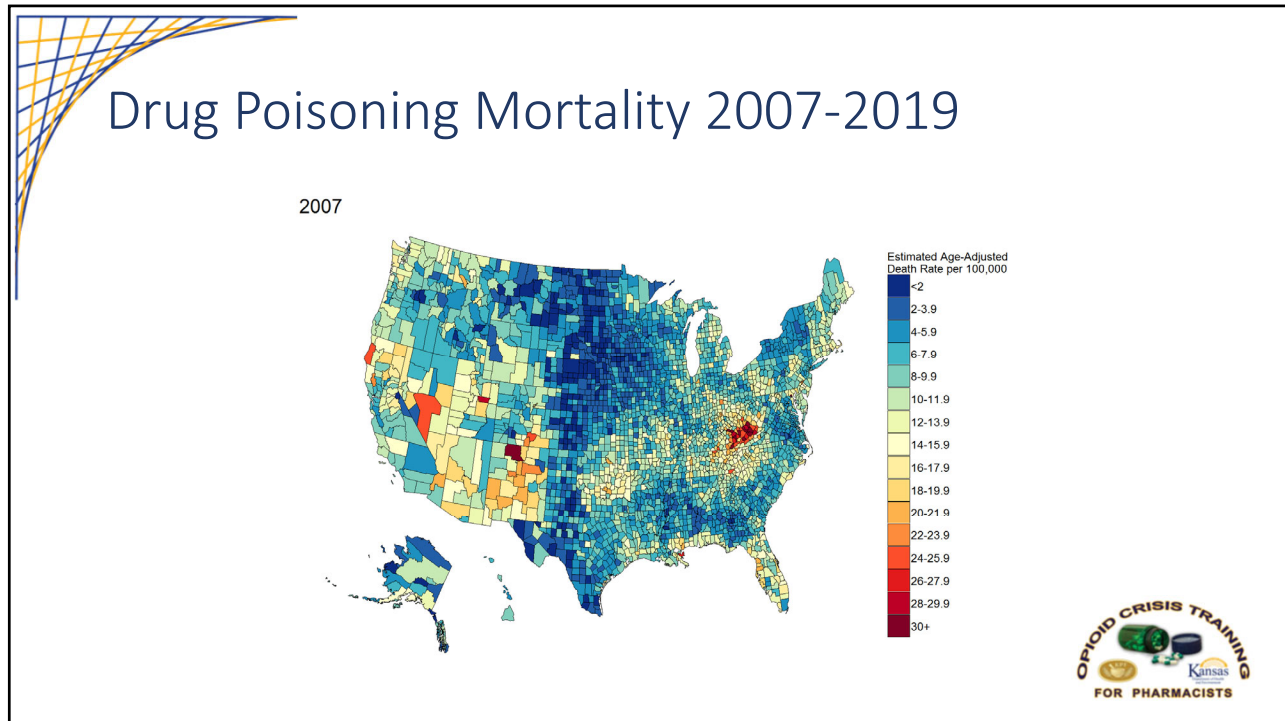


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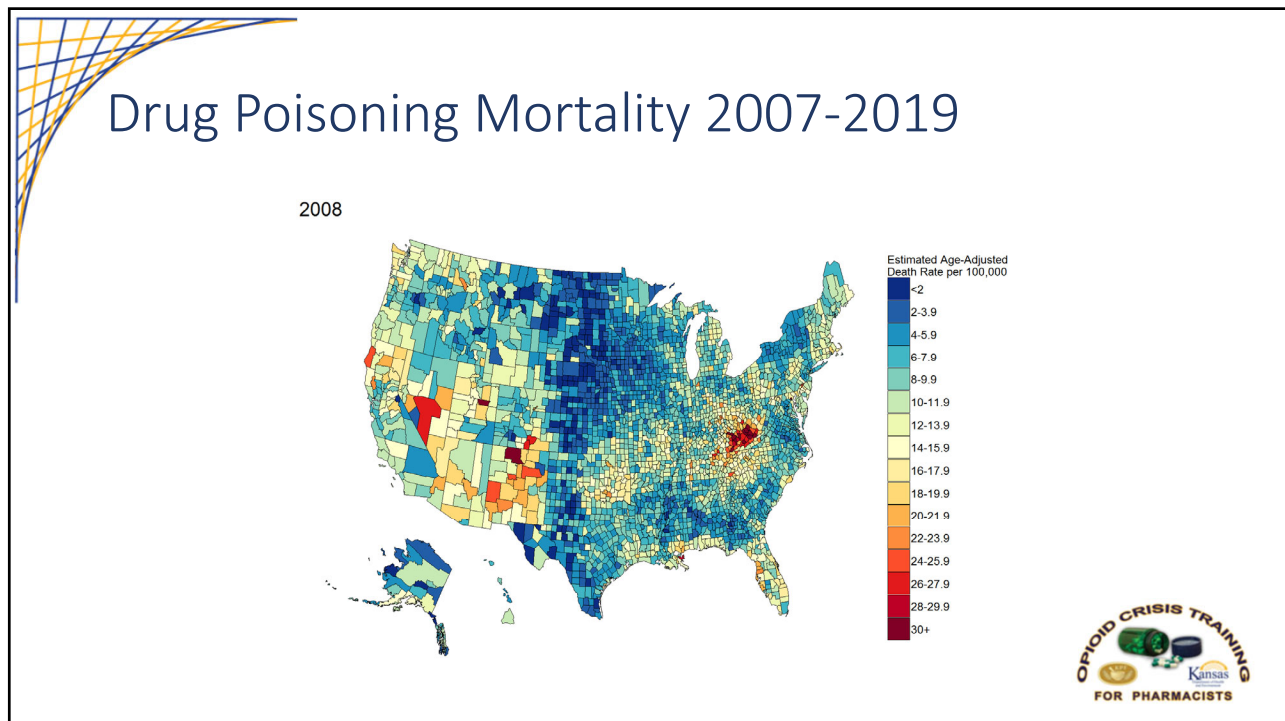
Opioid Use and Misuse – US Data



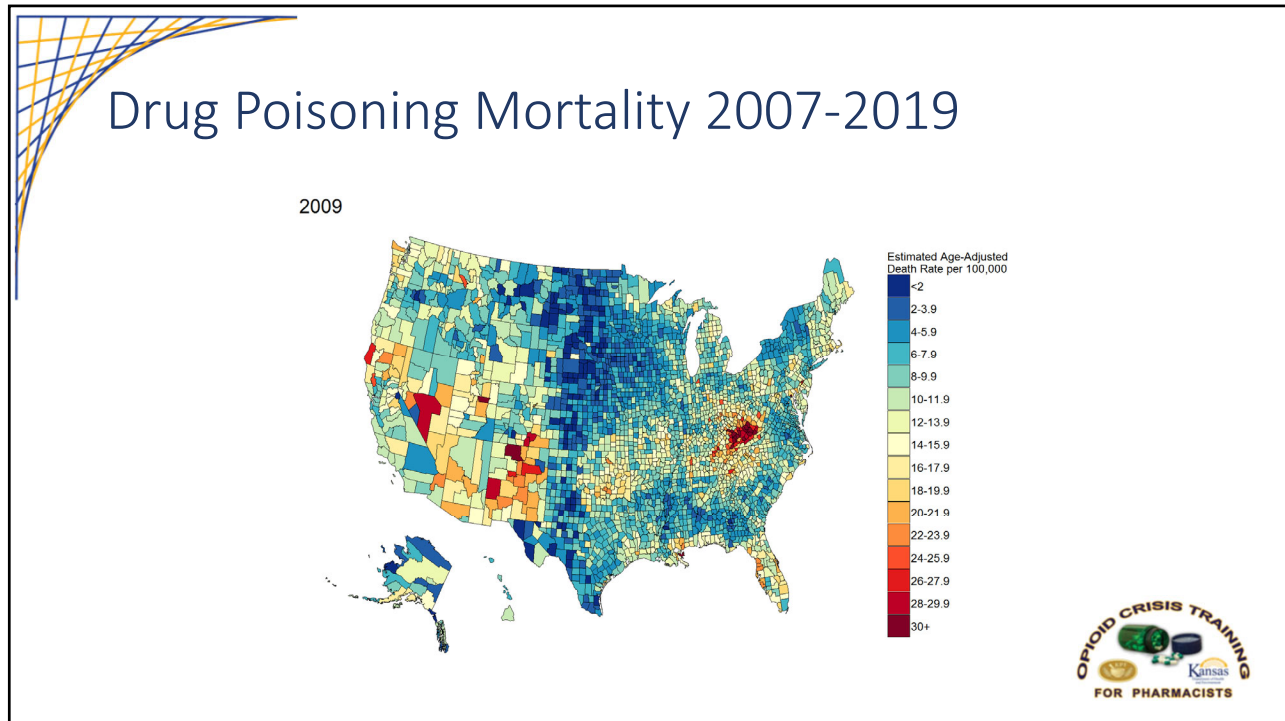
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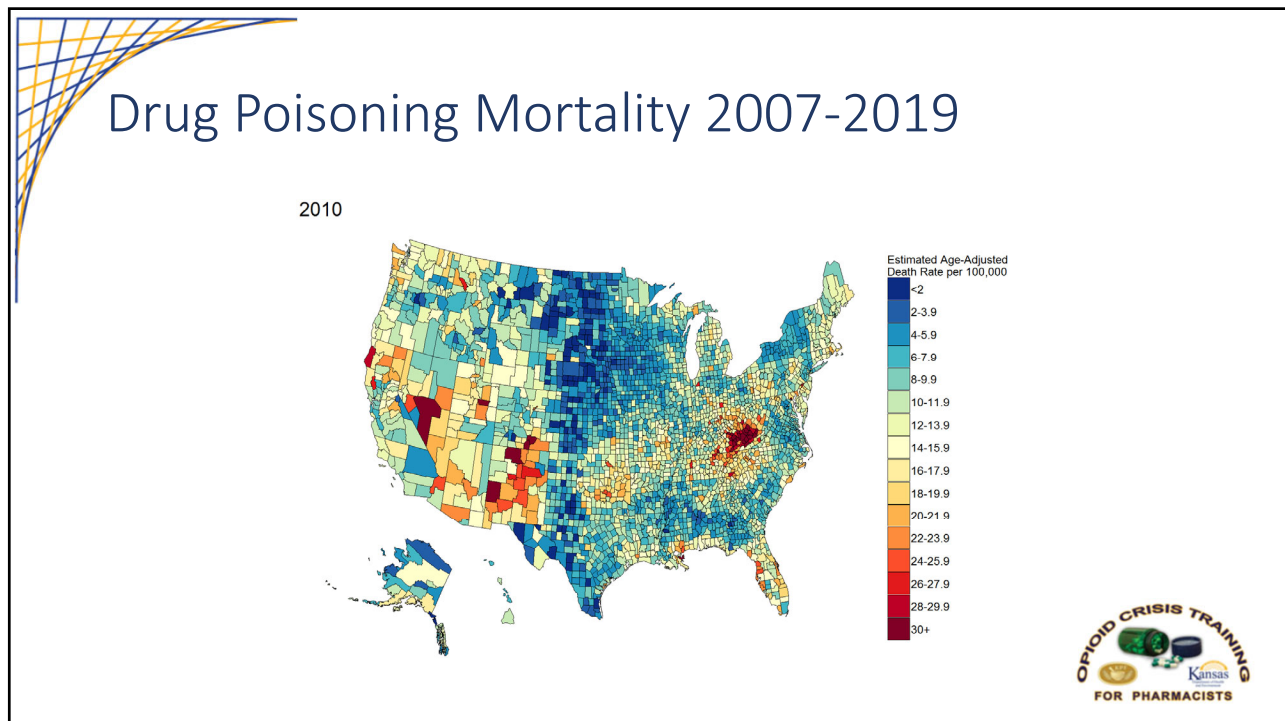
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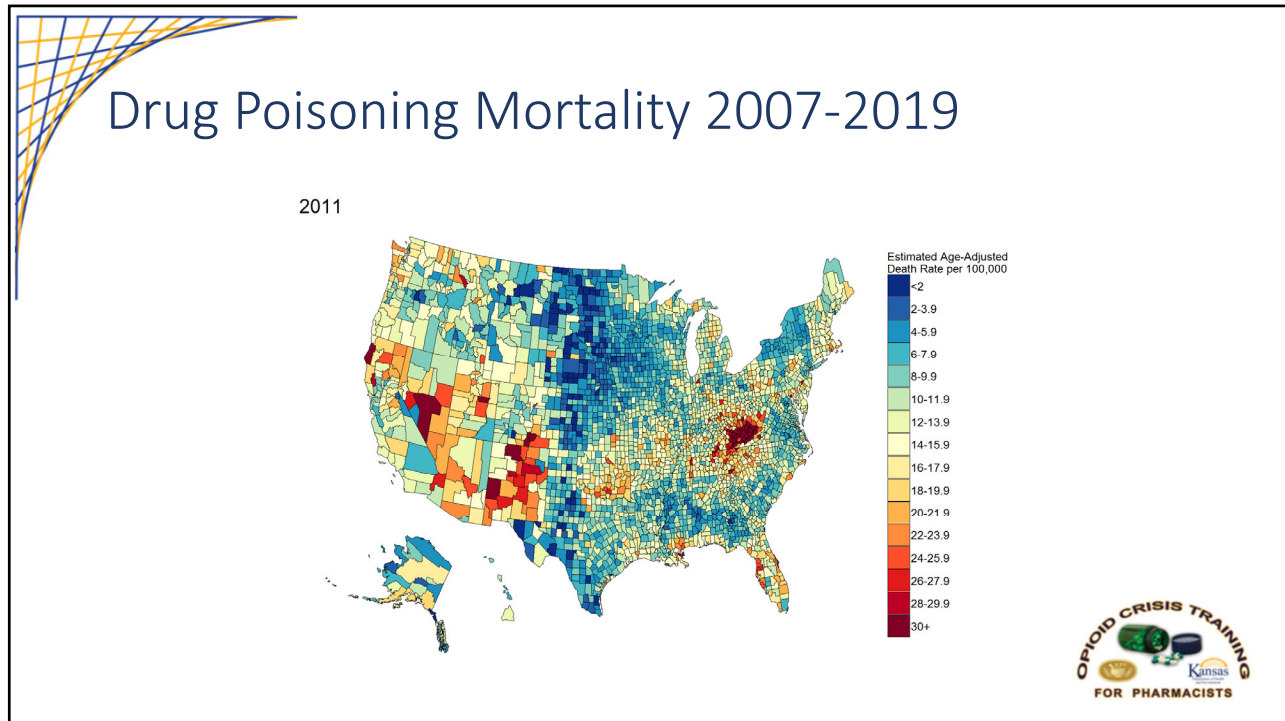
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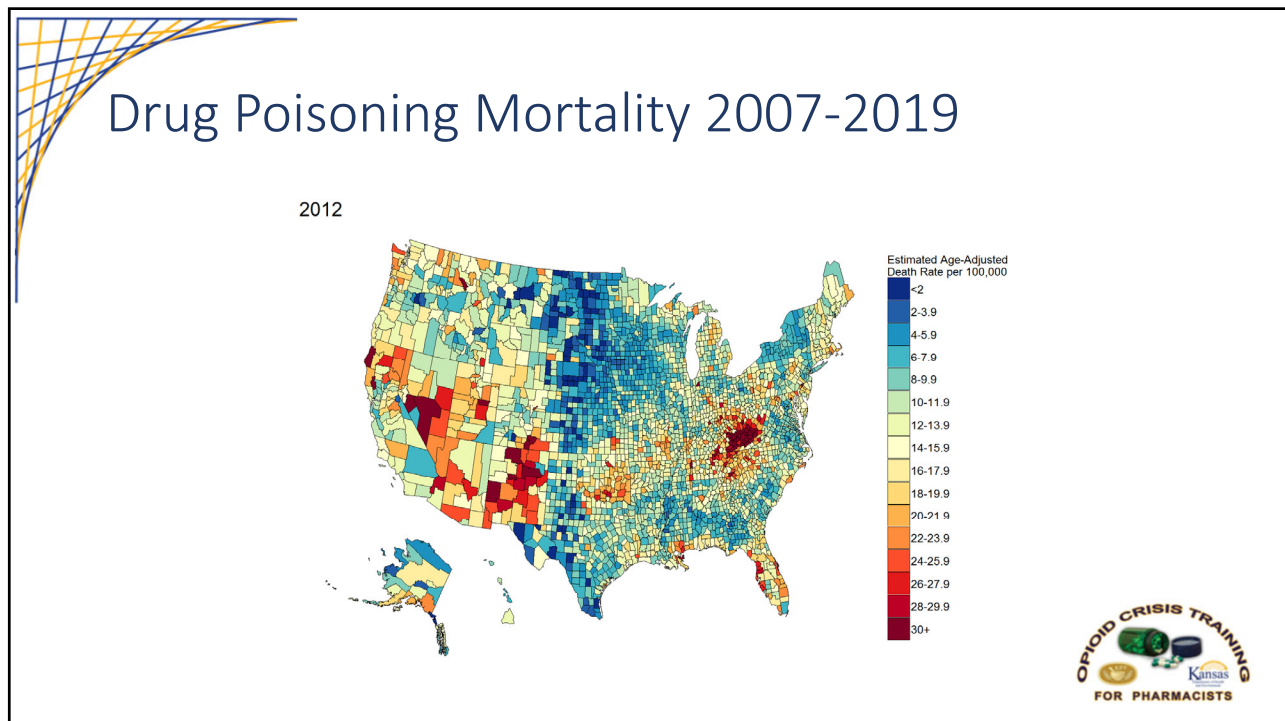
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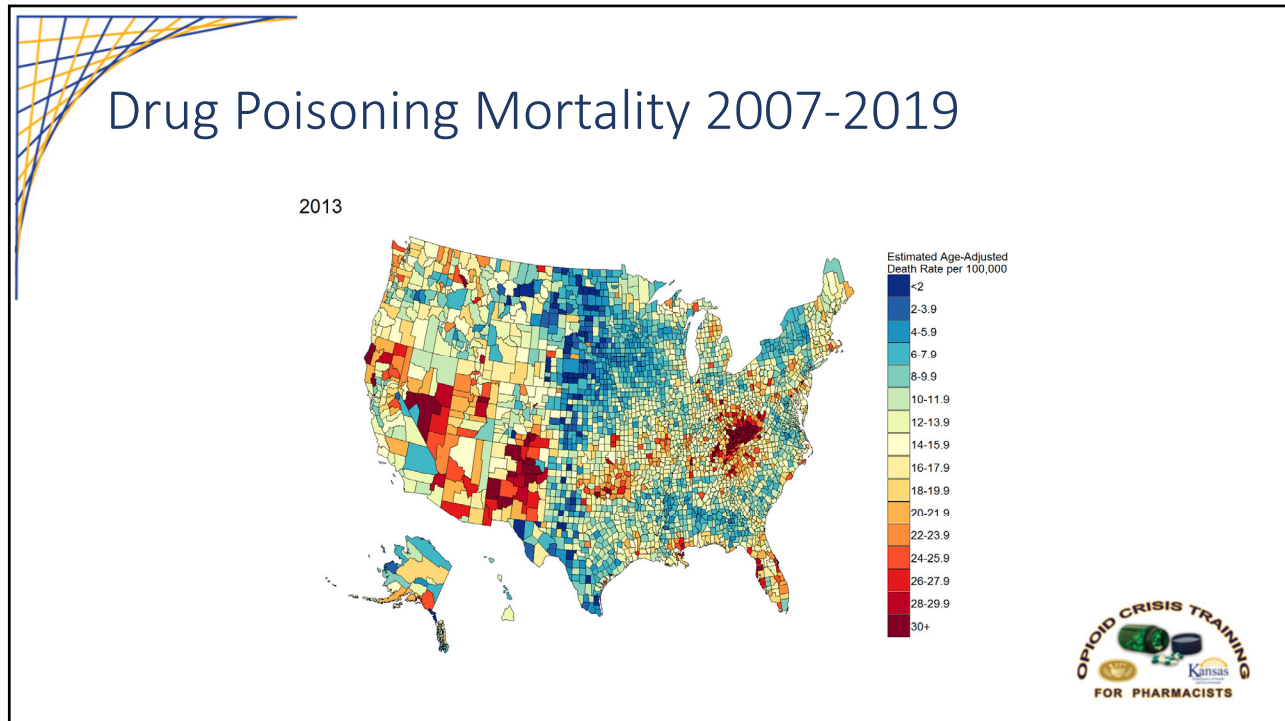
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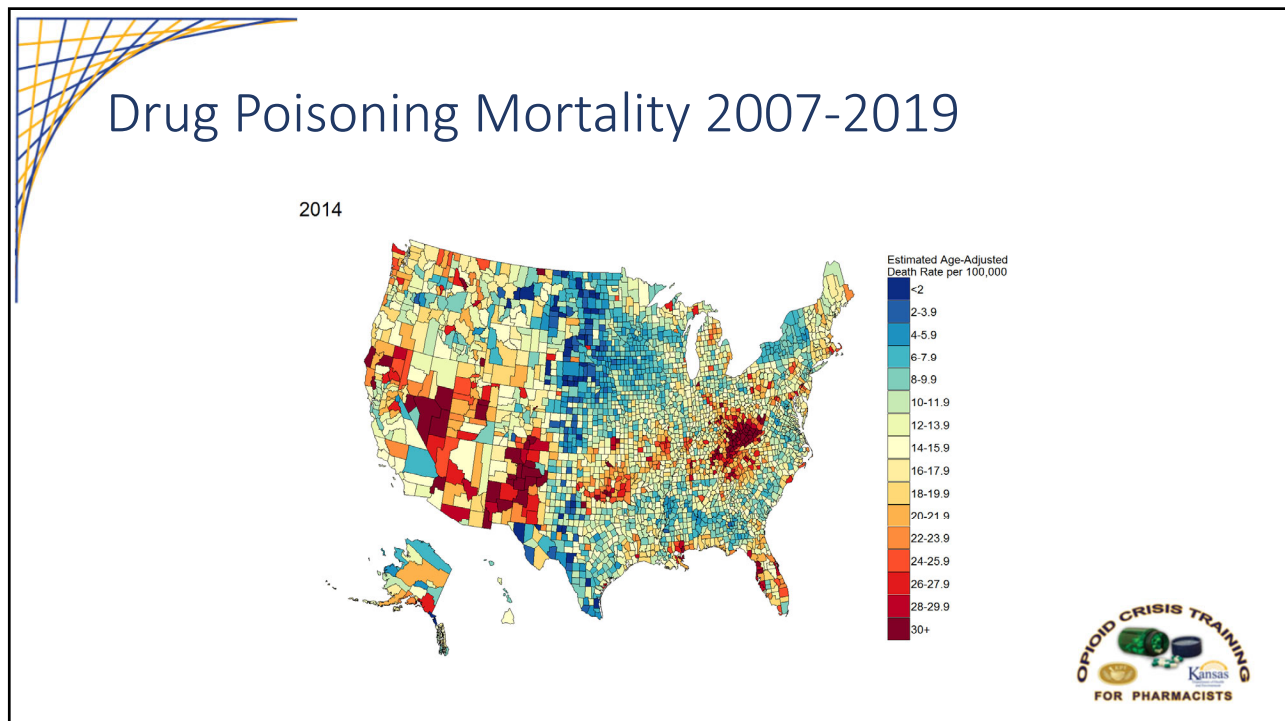
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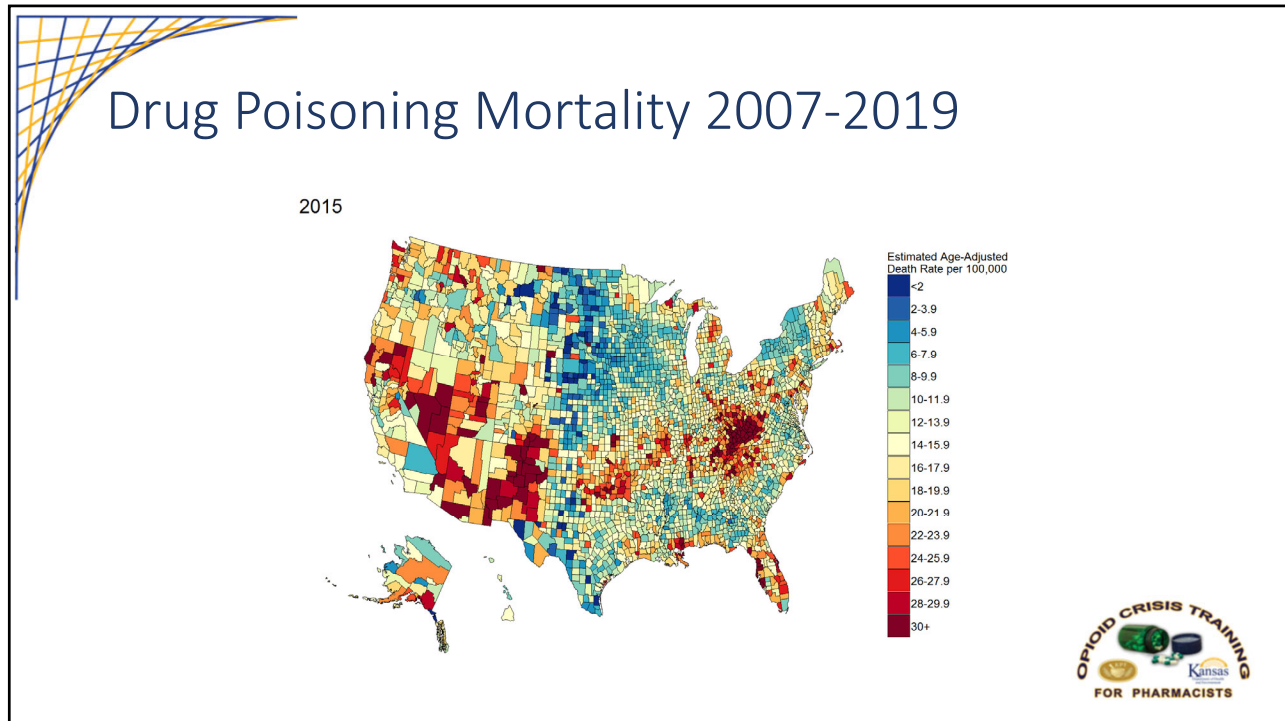
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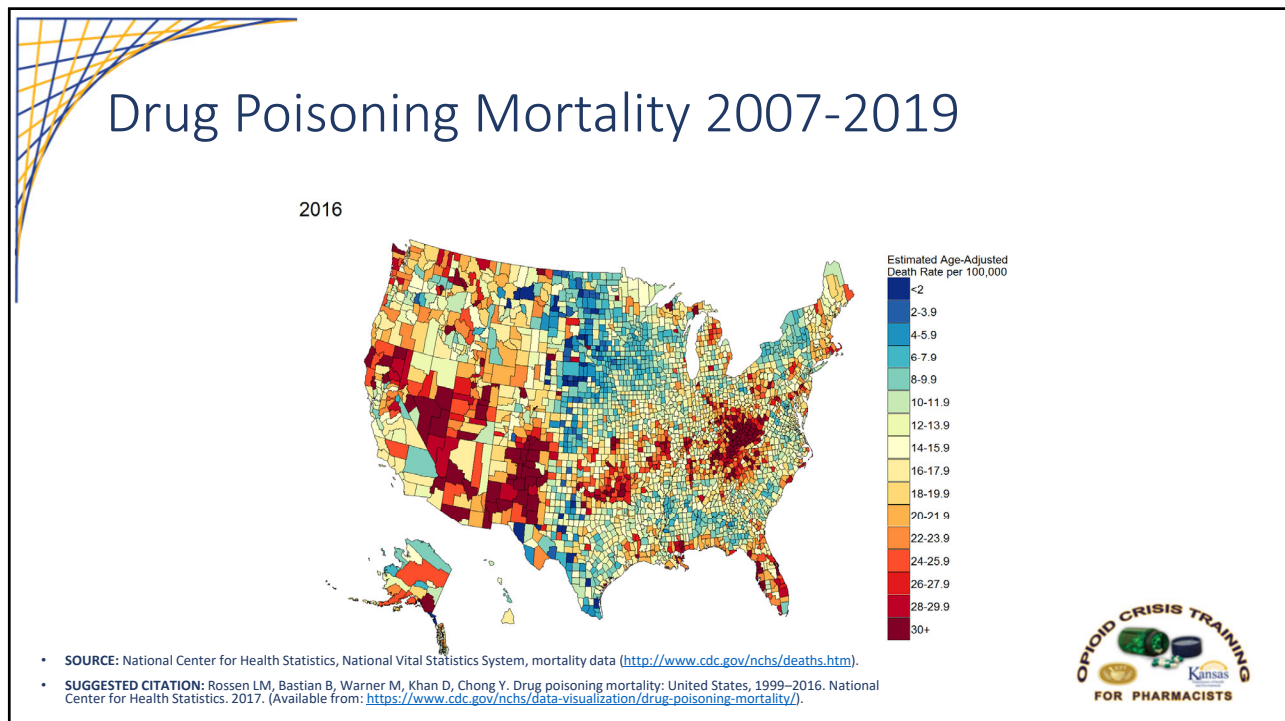
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Opioid Use and Misuse – US Data

- Payers in 2015
 - 76.4% of those hospitalized with an opioid related poisoning were either on Medicare, Medicaid or uninsured.
 - For those presenting at the ER the percentage was 73.1%

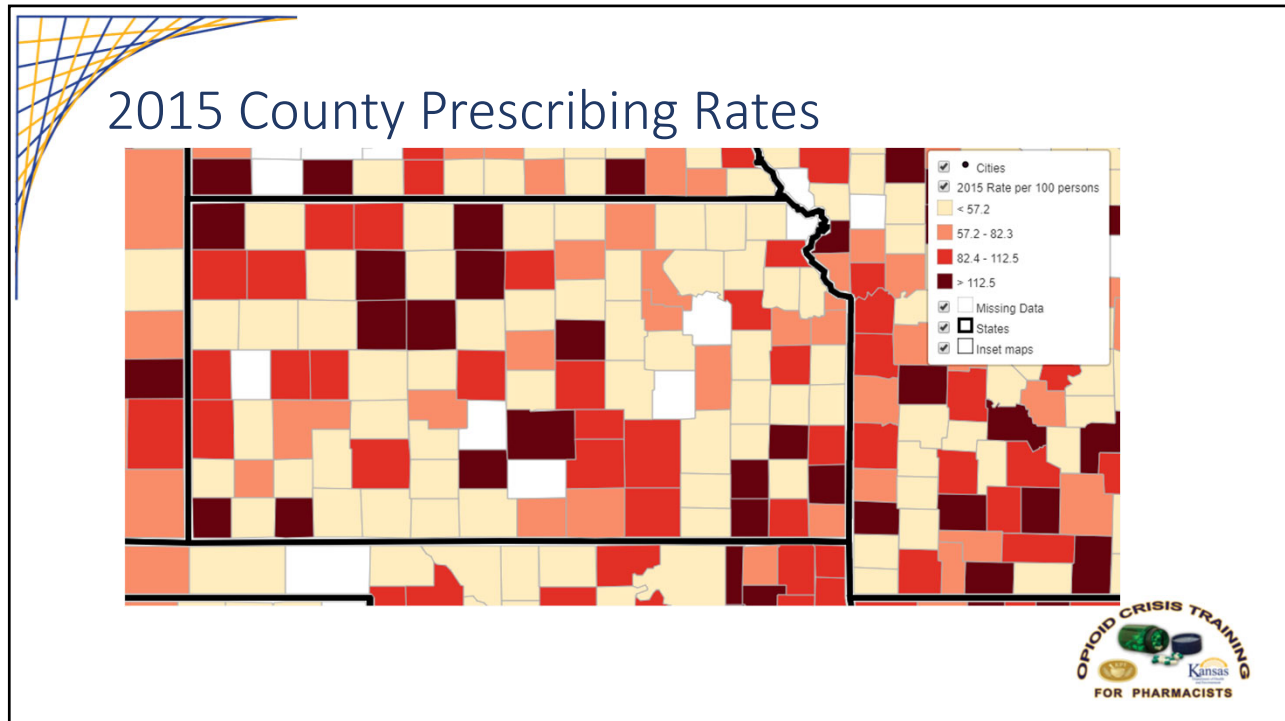


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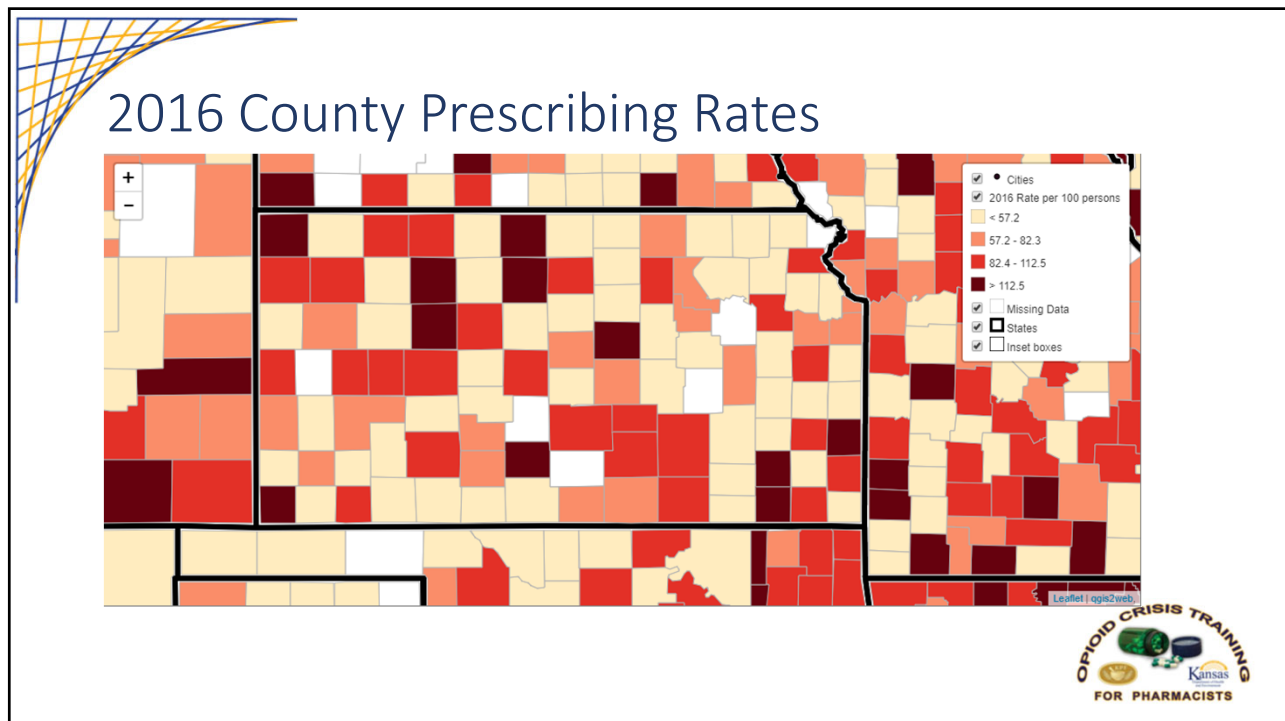
Opioid Use and Misuse – Kansas Data

- In 2016:
 - More than 2.2 million opioid prescriptions were written in Kansas
 - 76.9 prescriptions per 100 residents
 - 31.0 % higher than the US rate
 - Lowest in the state in last 10 years
 - 14.8% lower than the high of 90.3 experienced in 2012
 - Rates from county to county vary from 0.3 to 184.8 per 100 residents

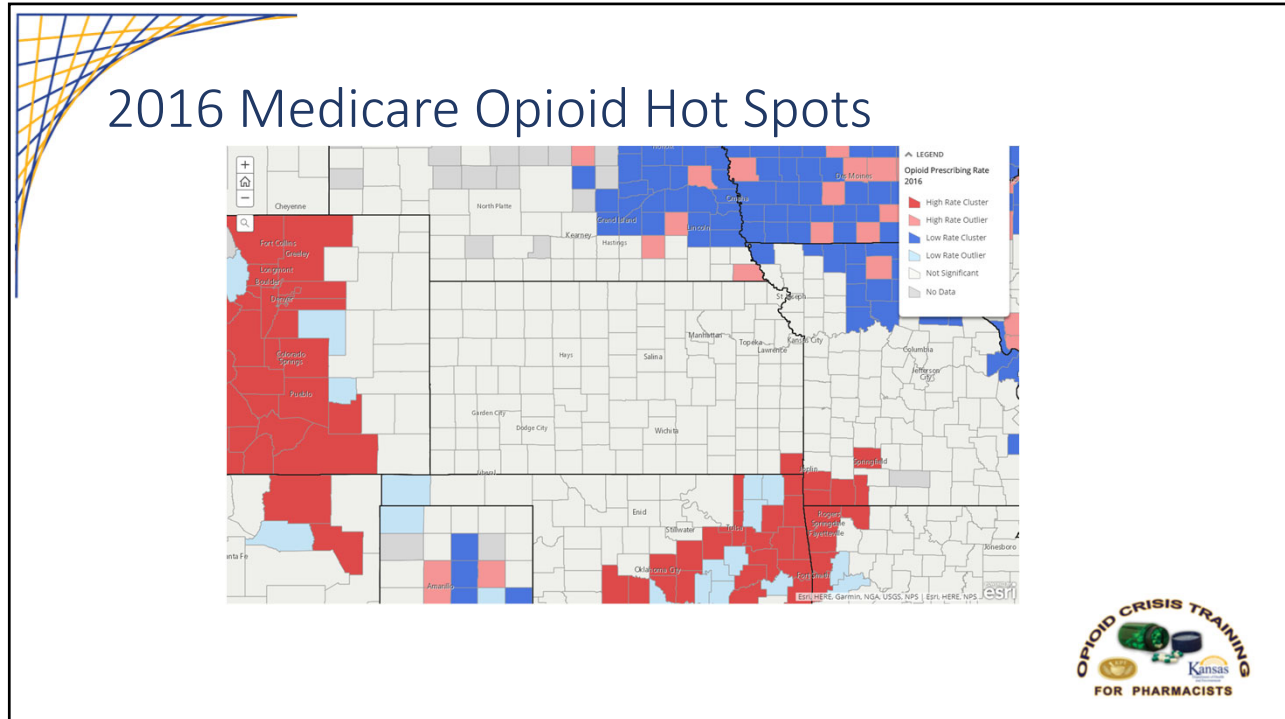




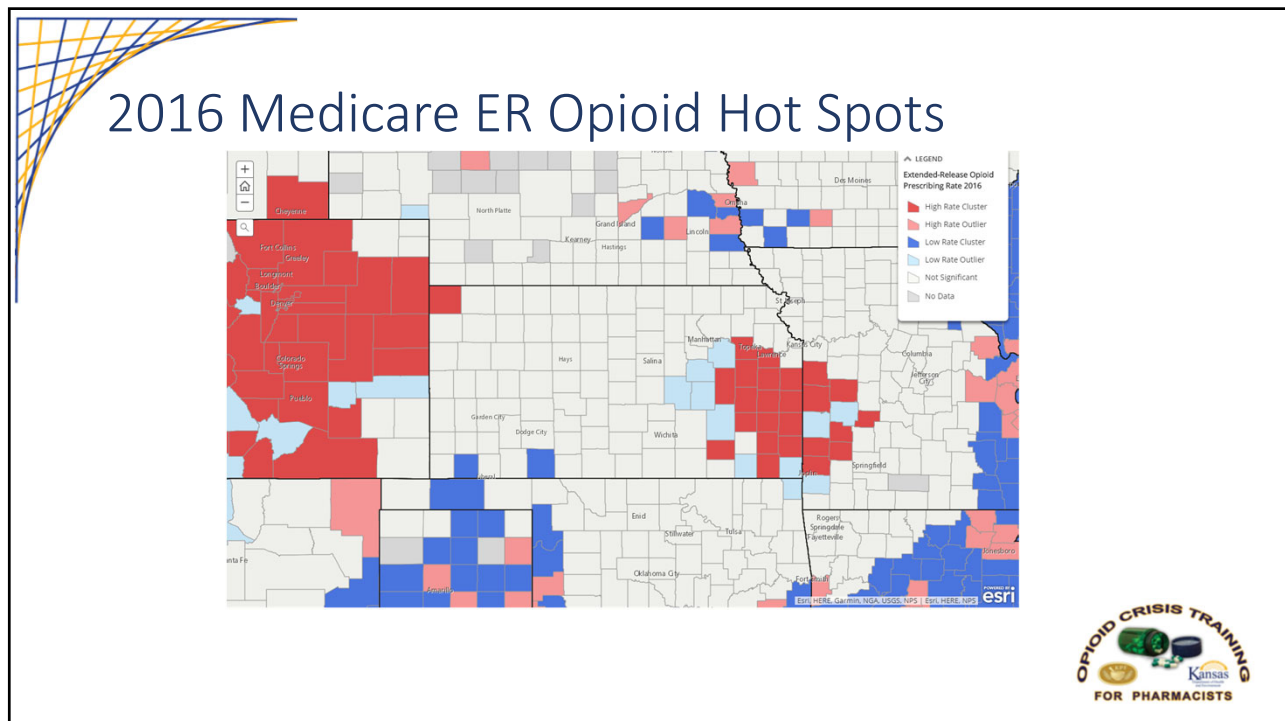
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Opioid Use and Misuse – Kansas Data

- In 2016:
 - 313 Kansans died as a result of an overdose
 - Lowest total since 2011
 - Crude death rate is 10.8 (US rate is 19.7)
 - Males 15-34 twice as likely to overdose and die from pharmaceutical opioids than females
 - Females 35-54 slightly more likely to overdose and die from pharmaceutical opioids than males



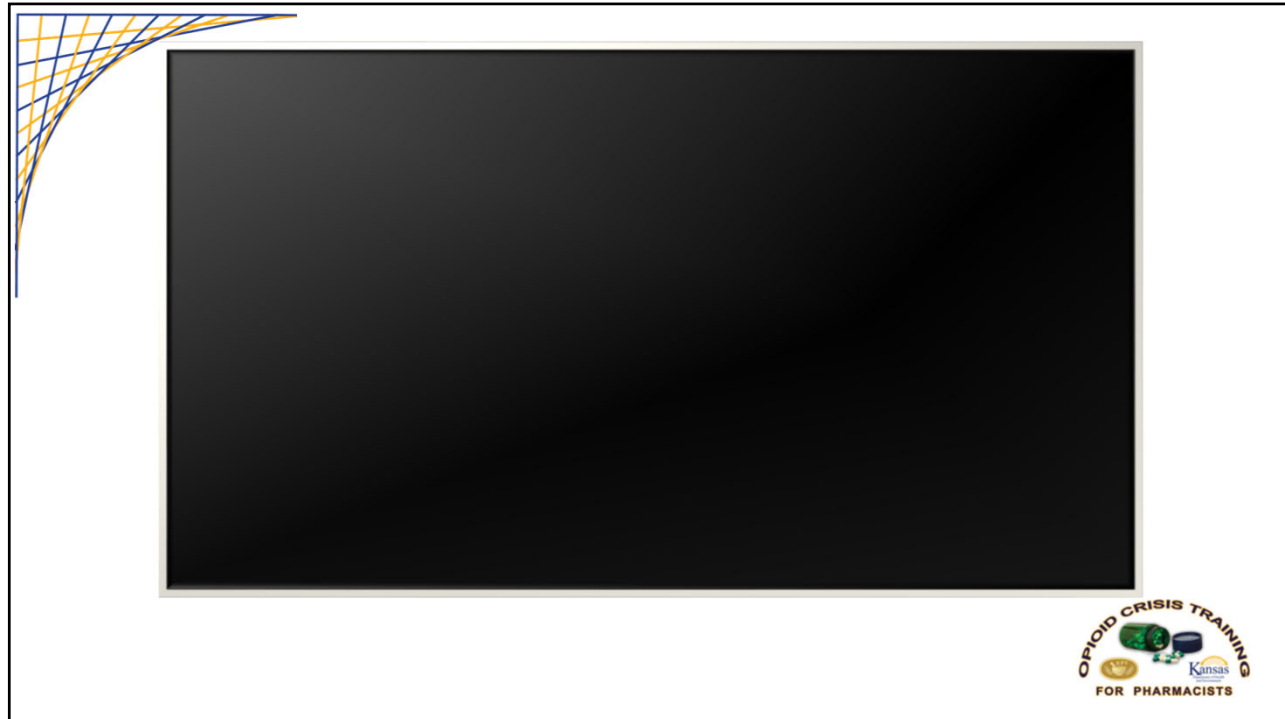
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Tools and Best Practices

- K-TRACS
- [CDC Guideline for Prescribing Opioids for Chronic Pain, United States 2016](https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf)
 - https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf
- KDHE – KanCare Opioid Policies
- Prescriber Outreach
- Patient Education
 - Storage
 - Disposal
- Refer to Behavioral Health




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K-TRACS – What It Is

- K-TRACS is the Kansas technology solution to support the Prescription Monitoring Program
- Designed to provide education and information to prescribers on their own prescribing trends as well as their patients controlled substance prescription histories
- Public health can use the data to monitor trends in prescribing and prescription utilization
- Can be used to alert prescribers, dispensers, and consumers to potential utilization problems that could indicate diversion or substance use issues



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K-TRACS – What It Is

- One of 49 PDMPs in the United States
- Gathers data from the pharmacy to present the most complete data available concerning patients
- Is the only method that shows what medications are actually making it into the hands of patients
- Currently undertaking a statewide process to integrate with other systems to minimize disruptions to workflow and to present information to those that need it in an optimal format
 - To sign up to participate in this program go to <https://www.pharmacy.ks.gov/k-tracs-responsive/k-tracs-statewide-integration>



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K-TRACS – What Must Be Reported

- Pharmacies servicing Kansans must report all schedule II-IV controlled substance prescriptions and of any drugs of concern that they dispense
- Drugs of concern in Kansas include:
 - Any product containing all three of these drugs: butalbital, acetaminophen, and caffeine;
 - Promethazine with codeine; and
 - Any item containing ephedrine or pseudoephedrine, its salts or optical isomers, or salts of optical isomers;
 - Gabapentin



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

K-TRACS – Data

- Data must be reported within 24 hours of dispensing
- Zero reports must be filed at a minimum of every 7 days
 - You will receive a confirmation email of your submission
- Can I get a waiver?
 - Yes, forms for waivers are available at www.pharmacy.ks.gov/k-tracs
- Information can be provided electronically through standards that adhere to the ASAP standard
 - If you do not have a system capable of creating an electronic report in the ASAP standard, you may submit information via paper on a specially provided form



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K-TRACS – Dos and Don'ts

- **Do** notify the program when your delegates quit so that they can lock their access
- **Do** discuss the reports with patients
- **Do** post patient notification posters
- **Do** contact the program if you have questions
 - PMPAdmin@ks.gov or 785-296-6547.
- **Don't** put your patient's reports in their charts/files
- **Don't** show your patients their reports (You can only discuss the report)
- **Don't** share reports with other pharmacists or prescribers
- **Don't** query anyone except your own patients
- **Don't** query prospective employees



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K-TRACS – Access

- Access to data in the system is limited to prescribers and dispensers
- Data in the system is not accessible by law enforcement
- Aggregated data is available to public health
- Medicaid can access data on an individual basis



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K-TRACS – Registering

- During registration you will:
 1. Create an account
 - You will provide a valid email and create a password

Log In

K-TRACS
Support: 1-855-544-4767

Registration Process Tutorial
Can't View This Mail? Our Address Booklet Reader

Register for an Account

Please create your own account and do not create an account on behalf of someone else.

Email

Password

Password Confirmation

Password Must

- Minimum of 8 characters
- Contain one upper case letter
- Contain one lower case letter
- Contain one special character (@ # \$ etc.)
- Maximum of 72 characters

Continue

Already have an account? [Log In](#)

[Need Help?](#)



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K-TRACS – Registering

- During registration you will:
 2. Select your role

Registration Process

Select your User Roles

▼ Healthcare Professional

- Physician (MD, DO, DPM)
- Dentist
- Nurse Practitioner / Clinical Nurse Specialist
- Physician Assistant
- Podiatric Physician (DPM)
- Optometrist
- Naturopathic Physician
- Pharmacist
- Psychologist
- Veterinarian
- Medical Intern
- Medical Resident
- IHS Prescriber
- IHS Dispenser
- Military Prescriber
- VA Prescriber
- VA Dispenser
- Pharmacy Technician
- Delegate



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K-TRACS – Registering

- During registration you will:
 3. Complete the application process
 - This includes basic demographic information, as well as your personal DEA number, NPI, drivers license, professional license number, license type, and controlled substance ID
 - Employer information includes DEA number, NPI and NCPDP/NABP number

All fields with an asterisk (*) are required.

| Personal | |
|--|----------------------|
| DEA Number(s) * | First Name * |
| <input type="checkbox"/> FW0807000 <input type="button" value="+ Add"/> | <input type="text"/> |
| DEA Numbers Added | Middle Name |
| <input checked="" type="checkbox"/> FW0807002 <input type="button" value="Autofill Form"/> | <input type="text"/> |
| <input checked="" type="checkbox"/> FW0807000 | Last Name * |
| ... or ... | <input type="text"/> |
| National Provider ID * | Date of Birth * |
| <input type="text"/> | <input type="text"/> |
| Drivers License Number * | |
| <input type="text"/> | |
| Professional License Number * | |
| <input type="text"/> | |
| License Type * | |
| <input type="text"/> | |
| Controlled Substance ID * | |
| <input type="text"/> | |
| Badge Number * | |
| <input type="text"/> | |

Complete Application Process

Some personal and employer information is required to gain access to PMP AWAYE.

- * Required fields will be indicated by a Red Asterisk *
- * In the Personal Section, Multiple DEA numbers can be entered if necessary

Save Time with Autofill

Use information from your DEA number to populate the form by clicking 'Autofill Form'. Information from that DEA number will be automatically filled into the rest of the personal information for you.

Scroll down to continue to the Employer Section.



K-TRACS – Registering

- During registration you will:
 4. Check for validation requirements
 - Any additional documents needed for validation will be requested from you in an email

The screenshot shows the registration interface. At the top right, a yellow box says "Your Registration is Not Complete" with a "Registration Process Tutorial" link. Below is a "Welcome" message. The "Your User Roles" section shows a table with columns for "Healthcare Professional", "Validation Documents Required", and "Documentation Received". Under "Physician (MD, DO, DPM)", the "Validation Documents Required" column shows a file named "rx_search_2015-04-08.pdf" with a red "Fill out the required form and upload it" button. The "Documentation Received" column is empty. Below this is the "Upload validation documents" section, which includes a "Check for Validation Requirements" box with instructions and "Back" and "Next" buttons. At the bottom right is the "OPIOID CRISIS TRAINING FOR PHARMACISTS" logo.

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K-TRACS – Registering

- During registration you will:
 5. Submit validation documentation

This screenshot shows the next step in the registration process. The "Your User Roles" table now shows a green checkmark in the "Documentation Received" column for the "Physician (MD, DO, DPM)" role. The "Upload validation documents" section shows a file named "2015-05-13_11-44-14.png" (75.3 KB) has been uploaded. Below the file list is an "Add File..." button. A yellow box titled "Submitting Validation Documents" provides instructions on how to submit forms and notes that a green checkmark will appear once documentation is uploaded. "Back" and "Next" buttons are at the bottom of this box. The "OPIOID CRISIS TRAINING FOR PHARMACISTS" logo is at the bottom right.

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KDHE-KanCare Opioid Policies

- Pain Management Prior Authorization (PA) for Short-Term/Acute Pain User (less than 90 days in last 120)
 - Limit of 7 day supply of short acting opioid
 - Up to 14 day supply with 60 look back period
 - No more than 7 days per prescription
 - Daily limit of 90 MME (morphine milligram equivalent)
 - PA required for all long-acting opioid prescriptions and any short-acting opioid prescriptions exceeding 90 MME limit



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KDHE-KanCare Opioid Policies

- Pain Management Prior Authorization (PA) for Chronic Opioid User (more than 90 days in last 120)
 - PA required for any duration
 - Patients with cancer, sickle cell, or hospice/palliative care diagnosis exempt from the 7 day supply and MME limits on long-acting PA
 - Buprenorphine products for opioid dependence are not affected by this policy



KDHE-KanCare Opioid Policies Grandfathering

- Current opioid users exceeding the initial 14-day supply within 60 days and/or doses greater than 90MME or the FDA-approved doses will be grandfathered
 - PA for these opioid users will occur in a phased-in manner
 - Members at doses > 120 MME will be grandfathered through March 5, 2019 (9 months grandfathering)
 - Members at doses up to 120 MME will be grandfathered through June 4, 2019 (1 year grandfathering)
 - The grandfathering is set for the dose and limits on effective date of policy. If the opioid prescription dose or limits are changed thereafter and PA criteria are not met, the original grandfathered PA will no longer be effective



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Prescriber Outreach

- When to contact prescriber:
 - Dosage significantly higher than necessary
 - Medication combination is risky
 - Consistently early refill requests
 - Contraindicated medications
 - You know the patient is visiting many prescribers/pharmacies
 - Prescription seems altered
 - Patient is demonstrating withdrawal symptoms



Prescriber Outreach

- Remember, if a patient is seeing multiple prescribers, you most likely know more about that patient's medications history through the use of K-TRACS than the prescriber
- In most cases the prescriber does not know if a patient is drug seeking, utilizing numerous prescribers/pharmacies, or taking their medications outside of recommendations
- As the rules around prescribing opioids become more restrictive, prescribers have more incentive than ever to ensure that their patients are receiving the most appropriate treatment
- If you see something, say something (ok that one is borrowed)



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Patient Education - Storage

- What to Tell Your Patient About Opioid Storage
 - Keep your prescription information leaflet
 - Keep in a cool, dry place
 - Keep away from any area that is accessible to children
 - If possible, lock them in a secure area
 - Discuss risks to other household members and guests and how to best address these risks

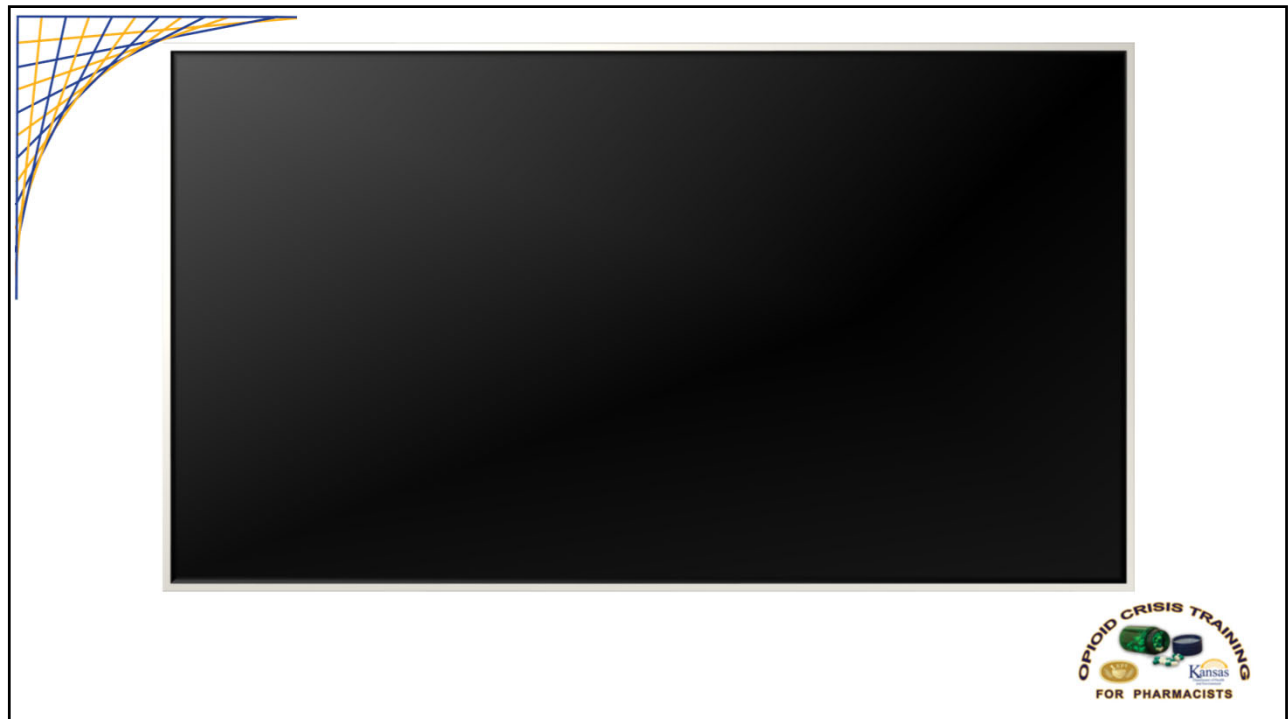


Patient Education - Disposal

- Disposal of Opioids
 - In-Pharmacy Take Back Programs
 - Community Drop Boxes
 - Community Take Back Programs
 - Household Disposal



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In-Pharmacy Take Back Programs

- Two Types
 1. Non-controlled substance take back programs
 2. Controlled substance take back programs



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In-Pharmacy Take Back Programs

- In order to run a pharmacy take back program for controlled substances, you must:
 - Be a registered site with the DEA
 - Buy and securely fasten an approved receptacle to a permanent structure
 - Have a sign indicating only schedule II-IV controlled substances and non-controlled substances are accepted
 - Sign must also indicate that no schedule I or illicit and dangerous substances are accepted
 - Not allow staff to handle the items, all materials must be placed in the container by the ultimate user



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In Pharmacy Take Back Programs

- The container you use must:
 - Be a permanent container
 - Have a removable liner
 - Have a opening large enough to accept material, but small enough to not allow removal of items without using a key
 - Be locked at all times, with the exception of when it is being emptied by staff



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In Pharmacy Take Back Programs

- The liner used in the container must be:
 - Waterproof
 - Tamper evident
 - Tear resistant
 - Clearly marked with liner size
 - Removable and sealable immediately upon removal without emptying or touching contents
 - Marked with a unique, trackable identification number



In Pharmacy Take Back Programs

- Once removed, the liner and all contents must be:
 - sealed and promptly destroyed, or;
 - delivered by a common or contract carrier to the registered location of a reverse distributor or distributor for destruction, or;
 - be picked up by a reverse distributor at your registered location
- Regardless of where it is destroyed it must be rendered non-retrievable



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In Pharmacy Take Back Programs

- To learn more please review Title 21 CFR Part 1317 Subpart C
- To modify your registration to allow you to provide a controlled substance take back program, please go to www.deadiversion.usdoj.gov



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

Community Drop Boxes

- A number of communities have opted to provide controlled substance drop boxes
 - These are usually located close to a public building such as a courthouse or police station
 - You can find out if there is either a community or pharmacy drop box close to you at any of the following sites:
 - <https://nabp.pharmacy/initiatives/awarxe/drug-disposal-locator/>
 - <http://rxdrugdropbox.org/map-search/>
 - <http://www.medreturn.com/medreturn-units/medreturn-locations/>



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Household Disposal

- If your patient cannot make it to a drop box, educate them about the safe ways to dispose of unwanted or expired medications at home
 - Deterra bag
 - Mixing with an unpleasant substance such as kitty litter or coffee grounds
 - Flushing if appropriate




<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>



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Household Disposal – Deterra Bags

- Deactivates prescription medications through an activated carbon compound
 - Renders them ineffective
 - Safe for the environment
 - Biodegradable
- Easy to use
 - Place unused meds in bag
 - Fill halfway with warm water
 - Seal tightly
 - Shake
 - Throw away in regular trash
- Comes in three sizes with capacity of pills, liquids or patches listed on the back of each bag



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

Household Disposal – Mix

- Patients can mix unused medications with undesirable materials such as kitty litter or coffee grounds
 - Add medications to warm water
 - Stir in with litter or other material, making a paste
 - Blend with a little more of the original material
 - Put material in container
 - Secure tightly
 - Throw in the trash



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Household Disposal – Flush

- Patients can simply flush their unused medications down the toilet
- FDA recommended products for flushing¹:

| Active Ingredient | Found in Brand Names |
|--------------------------------|--|
| Benzhydrocodone /Acetaminophen | Apadax |
| Buprenorphine | Belbuca , Bunavail , Butrans , Suboxone , Subutex , Zubsolv |
| Fentanyl | Abstral , Actiq , Duragesic , Fentora , Onsolv |
| Diazepam | Dialat / Dialat Acu Dial rectal gel |
| Hydrocodone | Anexsia , Hysingla ER , Lortab , Norco , Reprexain , Vicodin , Vicoprofen , Zohydro ER |
| Hydromorphone | Dilaudid , Exalgo |
| Meperidine | Demerol |
| Methadone | Dolophine , Methadose |
| Methylphenidate | Daytrana transdermal patch system |
| Morphine | Arymo ER , Embeda , Kadian , Morphabond ER , MS Contin , Avinza |
| Oxycodone | Combunox , Oxaydo (formerly Oxecta), OxyContin , Percocet , Percodan , Roxicet , Roxicodone , Roxybond , Targiniq ER , Xartemis XR , Xtampza ER |
| Oxymorphone | Opana , Opana ER |
| Tapentadol | Nucynta , Nucynta ER |
| Sodium Oxybate | Xyrem oral solution |



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>

Behavioral Health

- If you have a patient that is presenting with signs of addiction or misuse, please refer them to a local substance use disorder specialist
- SAMHSA – the Substance Abuse and Mental Health Services Administration – provides an updated list of known mental health providers in your area, including those that provide substance use disorder treatment
 - This resource is available at <https://findtreatment.samhsa.gov/>



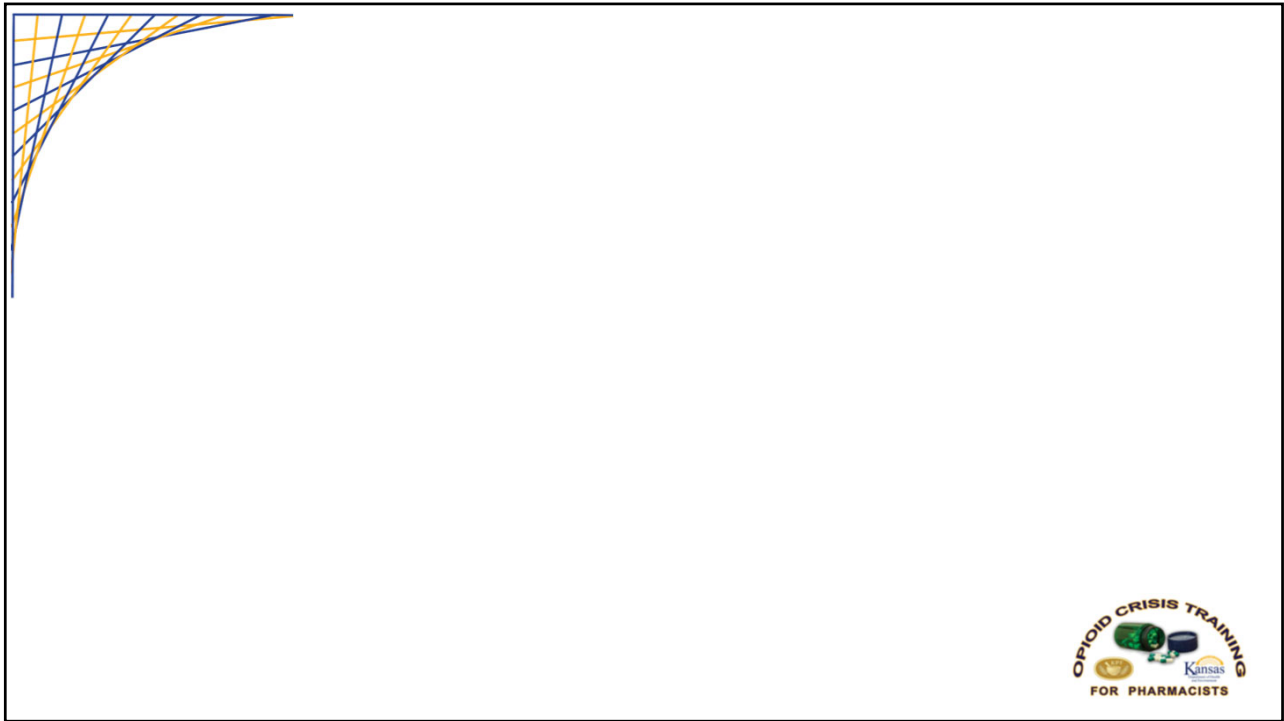
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More Information

- Additional information about opioids for pharmacies is available on the Kansas Pharmacy Foundation website:
 - <https://kansaspharmacyfoundation.org/educate/opioid-information-pharmacists.shtml>
- Additional data and national and state information is available on the CDC website:
 - <https://www.cdc.gov/drugoverdose/opioids/index.html>
- Additional state information can be found at:
 - <http://www.preventoverdoseks.org/>



<https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM588196.pdf>



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