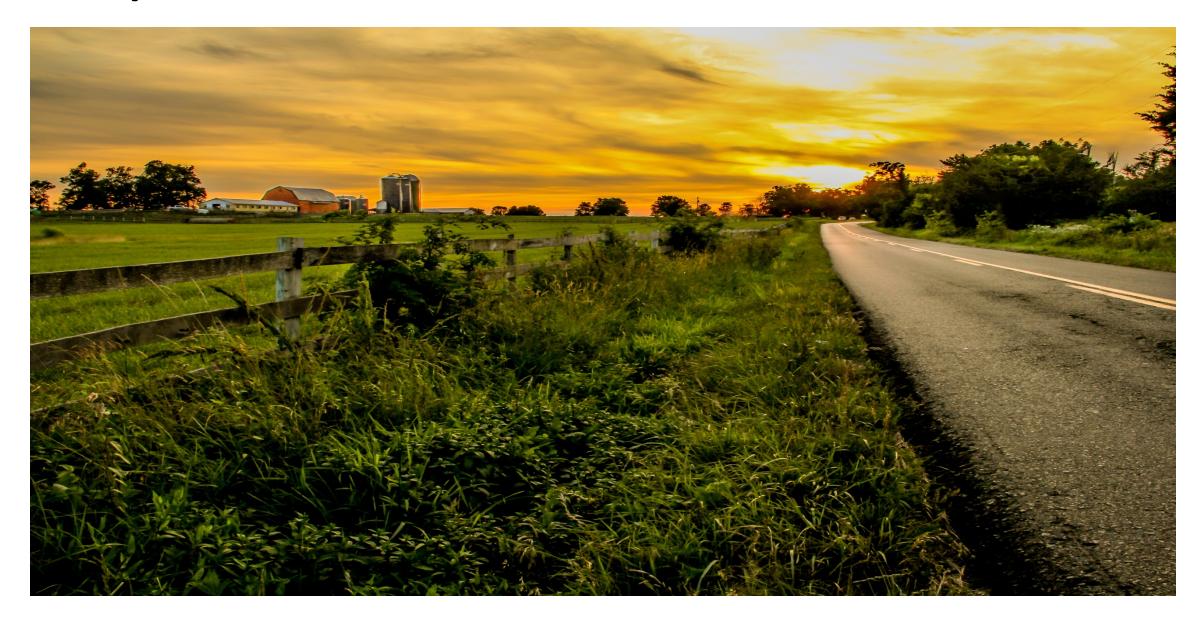
The Opioids Crisis in Rural America and Tribal Communities



The Opioid Crisis in Rural and Tribal Communities: Current Status and Future Directions

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U.S. Food and Drug Administration

October 26, 2017



Disclosures

• I have nothing to disclose.

Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

Objectives

- Review the current scope of the opioid crisis
- Discuss how opioids have impacted rural and American Indian/ Alaskan Native (AI/AN) communities
- Discuss FDA's actions related to opioids

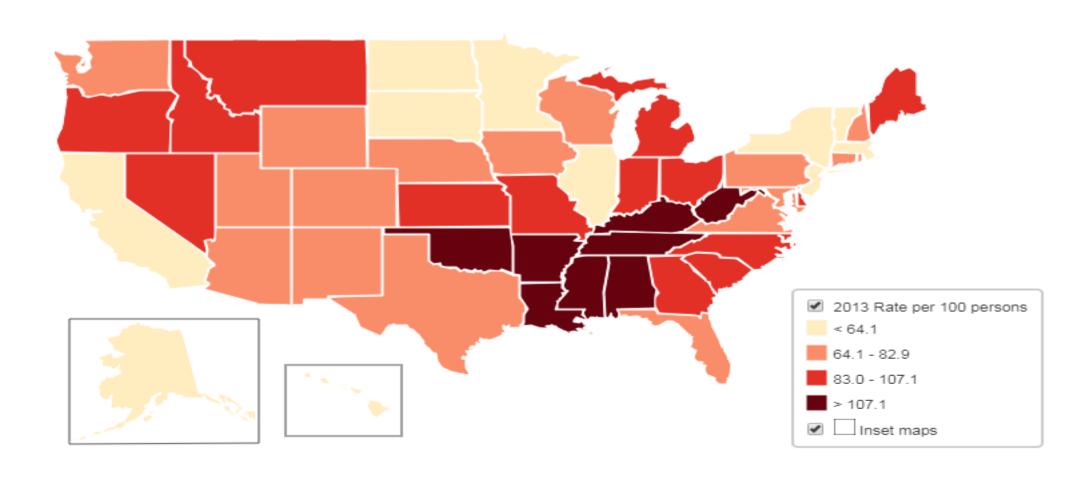
Where are we now?

- Almost 2 million Americans abused or were dependent on prescription opioids in 2014.¹
- An estimate 10 million people used prescription opioids for non-medical use in 2014.²
- There were 33,091 overdose deaths in the U.S. in 2015 from opioids.³
 - For perspective, this is about the average attendance of a Boston Red Sox game (33,792).⁴

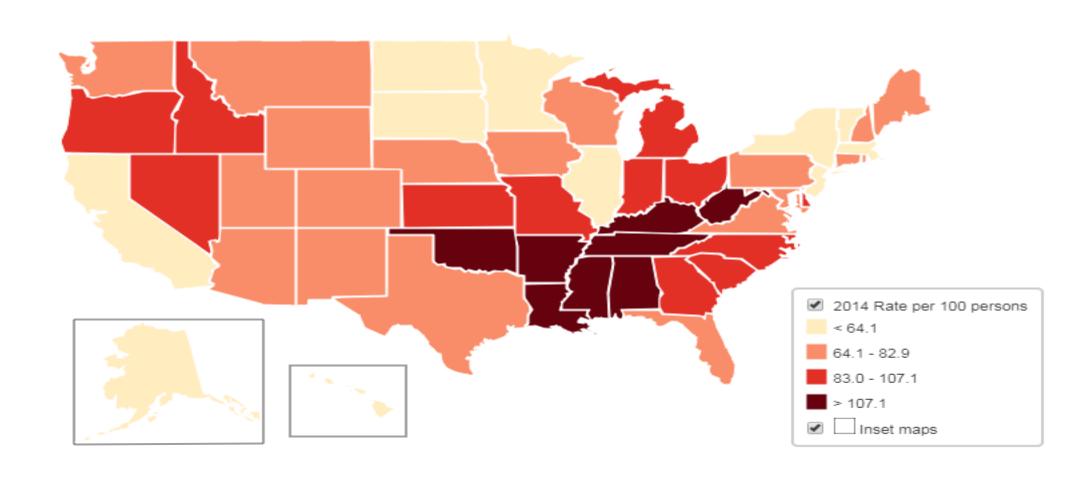
Prescribed Opioids pose a Risk beyond the Patient who receives the Prescription

- Among people who abuse prescription opioids, most get them
 - From a friend or relative for free (55%)
 - Prescribed by a physician (20%)
 - Bought from a friend or relative (11%)⁵
- Among new heroin users, about three out of four report abusing prescription opioids before using heroin.⁶

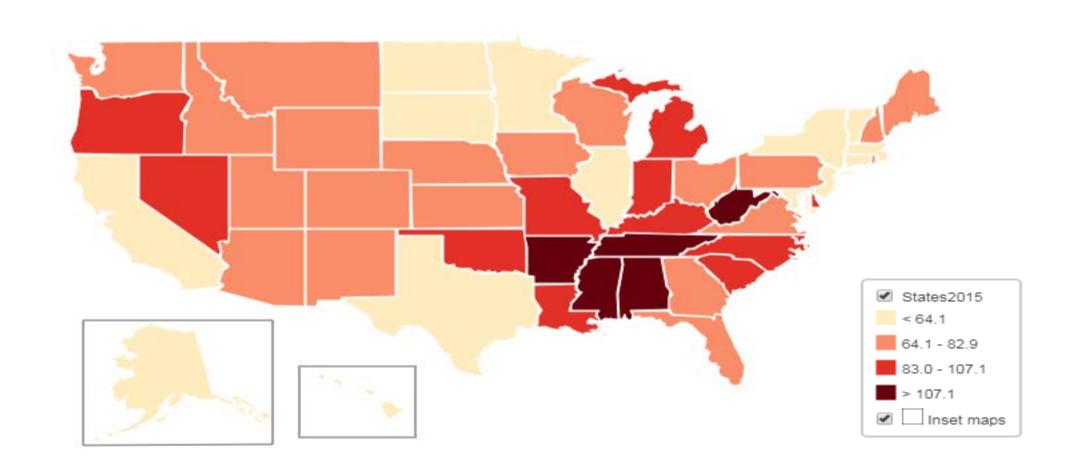
U.S. Prescribing Rates 2013⁷



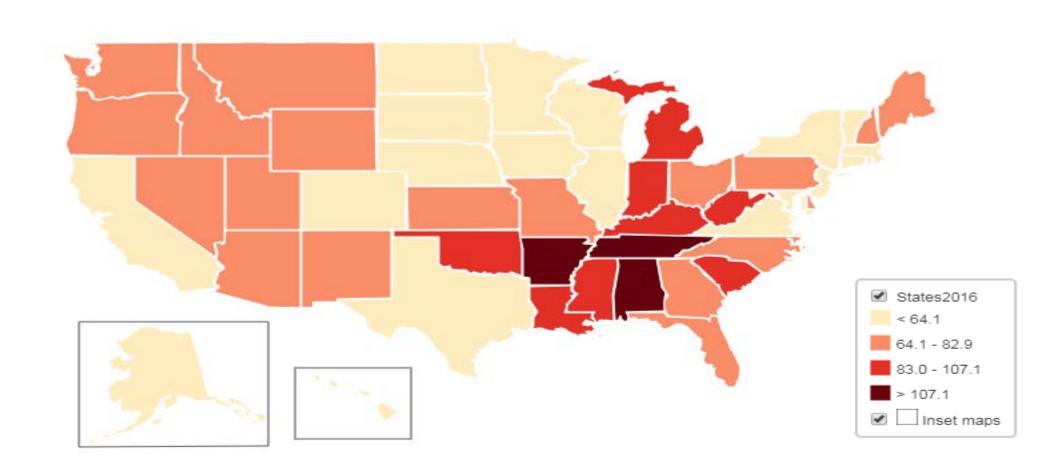
U.S. Prescribing Rates 2014



U.S. Prescribing Rates 2015

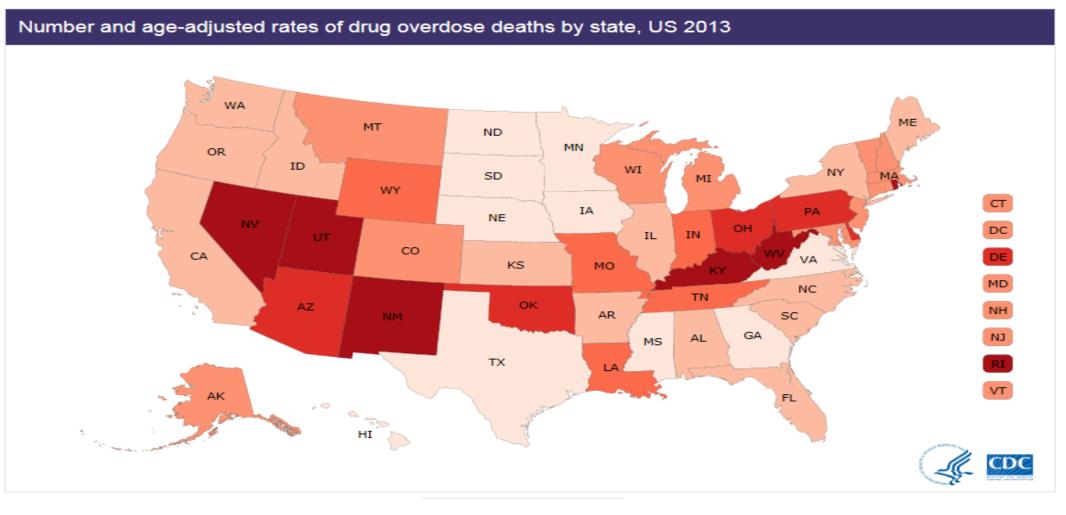


U.S. Prescribing Rates 2016



U.S. Prescribing Rates - Trends

- U.S. prescribing rates peaked in 2012 at 81.3 prescriptions per 100 persons⁷
 - Total: 255 million prescriptions
- Opioid prescribing has been decreasing between 2012 and 2016.
- U.S. prescribing rate in 2016 was 66.5 prescriptions per 100 people
 - 214 million prescriptions
- Rates continue to vary widely
 - Some counties had rates 7 times the national average



2.8 to 11.0
11.1 to 13.5
13.6 to 16.0
16.1 to 18.5
18.6 to 21.0
21.0 to 41.5

Maps: Drug Overdose Death Rate, CDC, see ref. 8

Number and age-adjusted rates of drug overdose deaths by state, US 2014 WA MT ND MN OR ID WI SD WY СТ IA NE NV ΙL IN UT CO CA VA KS МО NC TN ОК ΑZ AR NM SC GΑ AL MS TX LA FL 2.8 to 11.0

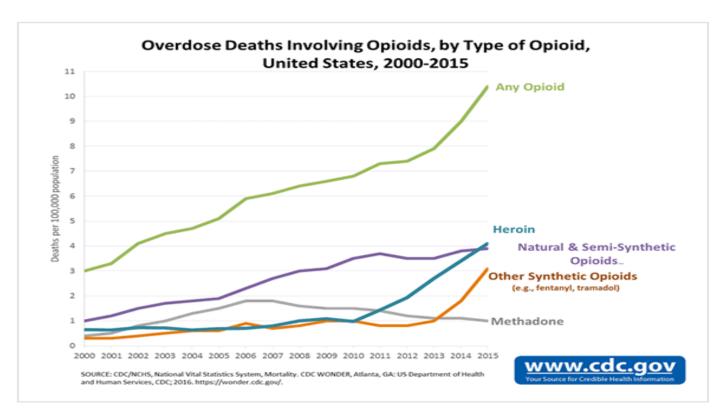


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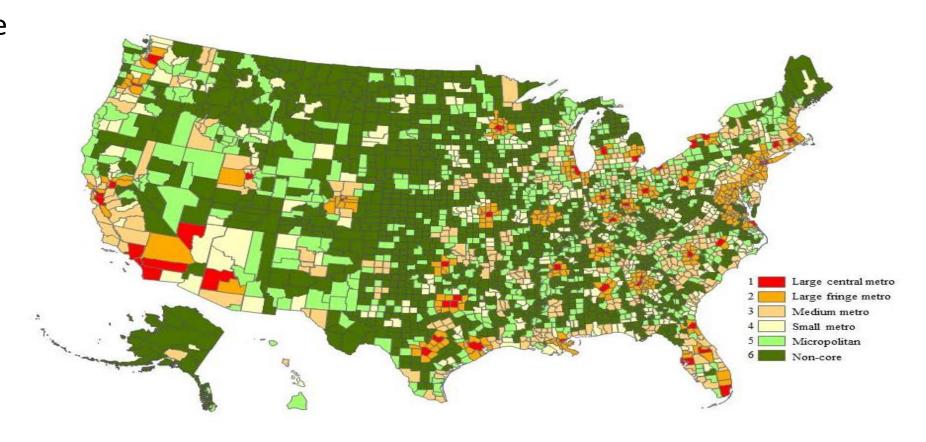
Overdose Deaths



- Deaths from opioids continue to increase
- Deaths from heroin and fentanyl appear to be increasing at a faster rate⁹
 - Fentanyl deaths are likely 2° illicitly manufactured fentanyl
- Since nearly 80% of heroin users report using prescription opioids prior to heroin, deaths from prescription and illicit opioids are inherently linked.¹⁰

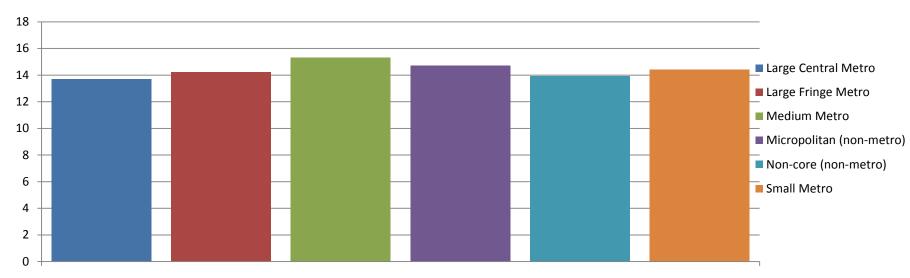
How are Counties Classified?

- 63% of countries are "non-metropolitan" (green on the map)
- 15% of the U.S. population¹¹





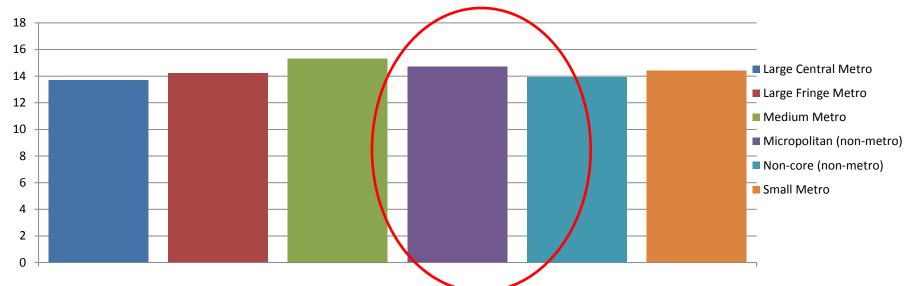
Drug Overdose Deaths by Urbanization



Urbanization (2013)	Drug Overdose Death Rate
	per 100,000
Large Central Metro	13.7
Large Fringe Metro	14.2
Medium Metro	15.3
Small Metro	14.4
Micropolitan (non-metro)	14.7
Non-core (non-metro)	13.9
Total	14.3



Drug Overdose Deaths by Urbanization



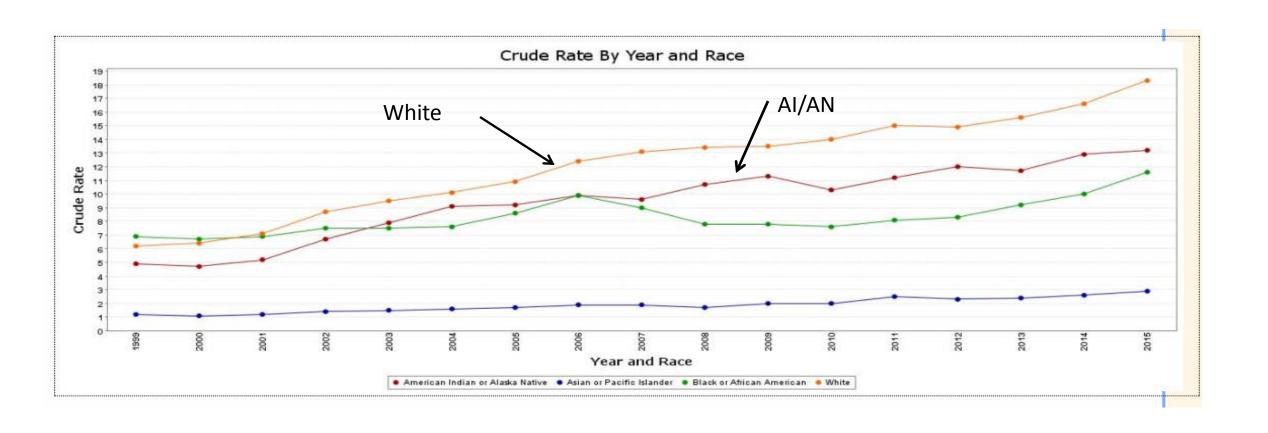
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	1.
Total	14.3
I	

• Drug overdose death rates for 2011 – 2015 are similar across different levels of urbanization. 12

Prescribing in Rural Areas

- Prescribing has been decreasing in both rural and urban areas.
- However, prescribing rates have decreased less in rural areas.
- Prescribing rate in rural areas is 53% higher
 - 11.8 compared to 7.8 prescriptions per 100 persons per month. 13

AI/AN Drug Overdose Death Rates



Deaths among AI/AN

- Drug related deaths: rate of these deaths increased from five per 100,000 population (adjusted) in 1989-1991 to 22.7 per 100,000 in 2007-2009.
- death from prescription opioid overdose among American Indian or Alaska Natives further increased almost four-fold from 1.3 per 100,000 in 1999 to 5.1 per 100,000 in 2013.¹⁵

Opioid Use among AI/AN Youth

- Al/AN 8th, 10th, and 12th graders had higher rates of substances abuse compared to a nationally representative sample from the Monitoring the Future survey (years 2009 -2011).
- 12.0% of AI/AN 12th graders had used "narcotics"
- 2.6% had used heroin¹⁶

Challenges for Rural and Tribal Communities

- Geographic
 - Geographic isolation
 - Limited transportation options
- Socio-economic
 - Increased economic stress
 - Chronic pain and injury are more common in rural areas¹⁷
- Medical System issues
 - Higher prescribing rates
 - Limited access to treatment programs/ treatment providers¹⁸
 - Decreased naloxone access¹⁹
 - Lengthy EMS response time
 - Difficulty accessing Emergency Care
- Stigma
 - Increased chance you personally know someone at treatment center²⁰

Different Communities may face Different Challenges

"Such findings point to an important consideration – that the causes and implications of rural drug use are highly variegated and may be as different from one region to another, or even one county from another, as they are from generalized urban trends."

-Dombrowski, et al. "Current Rural

Drug Use in the US Midewest"21

What is FDA doing about Opioids?

- FDA has taken numerous actions to address risks associated with opioid use, misuse, and abuse.
- Opioid safety is not a new area for FDA FDA's actions regarding opioid risks date back at least 15 years.²²
- FDA developed an Action Plan in 2016 aimed at reversing the epidemic while still providing patients in pain with access to relief.²³
- Dr. Gottlieb, our current commissioner, immediately made identifying additional and more forceful steps that FDA can take to address the opioid crisis his highest priority.

FDA Actions

- Expand the use of Advisory Committees
- Develop warnings and safety information for immediate-release (IR) opioid labeling
- Strengthen postmarket requirements
 - Better evidence on the risks of misuse and abuse associated with long-term use
- Update Risk Evaluation and Mitigation Strategy (REMS) Program
 - Increase the number of providers who receive training on pain management and safe prescribing
 - September 28, 2017: FDA letters sent to 74 manufacturers of immediate release opioids, notifying them that their drugs will now be subject to more stringent requirements under a REMS

FDA Actions

- Incentivize the development of opioid medications with progressively better abuse-deterrent properties and support their widespread use.
 - Abuse-deterrent is not abuse-proof
- Support better treatment
 - Making naloxone more accessible
- Reassess the risk-benefit approval framework for opioid use
 - Incorporating the broader public health impact of opioid abuse into approval decisions

FDA Opioid Policy Steering Committee

- Established by Dr. Gottlieb to bring together senior agency leaders to "explore and develop additional tools or strategies FDA can use to confront this crisis."²⁴
- FDA welcomes your comments. There is a public docket for you to submit ideas, suggestions, or recommendations.²⁵
 - Comments can be submitted until December 28, 2017

FDA Opioid Policy Steering Committee

FDA is particularly interested in 3 areas:

- 1. What more can FDA do to ensure that the full range of available information, including about possible public health effects, is considered when making opioid-related regulatory decisions?
- 2. What steps can FDA take with respect to dispensing and packaging to facilitate consistency of and promote appropriate prescribing practice?
- 3. Should FDA require some form of mandatory education for health care professionals who prescribe opioids?



Solutions will need to come from many Sources

"This crisis has gotten so large and pervasive that it is simply beyond the scope of any one of our agencies to make a meaningful impact. It is only by working together and in partnership with state and private entities that we are going to slowly reverse the trend of new addiction..."

Scott Gottlieb, FDA Commissioner²⁶
 Testimony to the Senate Committee on Health, Education
 Labor and Pensions
 October 5, 2017

Thank You

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- 4. http://www.espn.com/mlb/attendance/ /sort/allAvg (2017 season)
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- 25. https://www.federalregister.gov/documents/2017/09/29/2017-20905/opioid-policy-steering-committee-establishment-of-a-public-docket-request-for-comments
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End of Presentation





The Opioid Epidemic: The Indian Health Service Response to a National Crisis

IHS Heroin, Opioids, and Pain Efforts (HOPE) Committee

Dr. Beverly Cotton, DNP, RN, CPNP-PC Director, Division of Behavioral Health Indian Health Service Headquarters

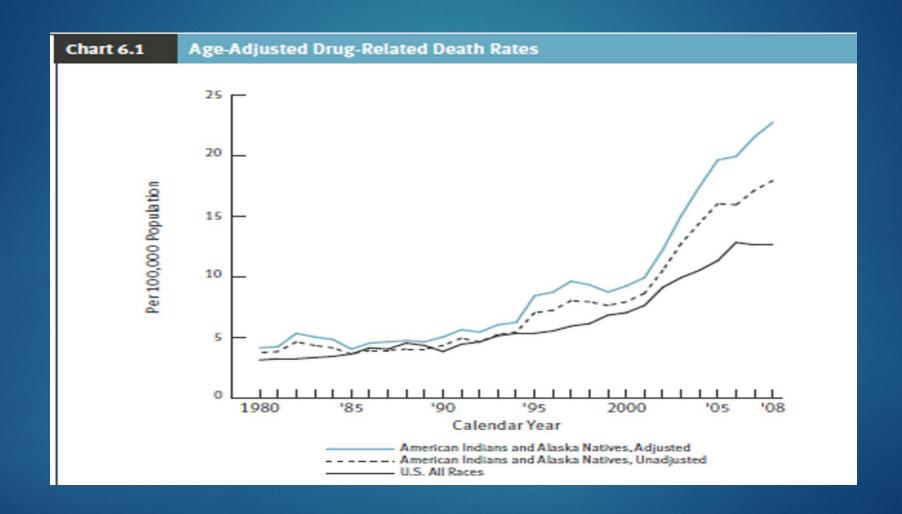
Mission

"To raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level"





Drug-Related Death Rates



National Committee on Heroin, Opioids, and Pain Efforts (HOPE)

- ► New IHS Committee created in March 2017
- Evolved out of the Prescription Drug Abuse Workgroup
- Membership: physicians, pharmacists, behavioral health providers, nursing consultation, and epidemiologists
- Purpose:
 - Promote appropriate and effective pain management.
 - Reduce overdose deaths from heroin and prescription opioid misuse.
 - Improve access to culturally appropriate treatment.

Policy Efforts

- ▶ IHM Part 3, Chapter 30- Chronic Non-Cancer Pain Management
 - Published in June 2014.
 - Provides best practice guidelines surrounding management of chronic non-cancer pain.
 - ► Currently under revision to ensure alignment with CDC Guideline for Prescribing Opioids for Chronic Pain- United States, 2016.
- ▶ IHM Part 3, Chapter 32- State Prescription Drug Monitoring Programs
 - Published June 2016.
 - ► Establishes requirement for IHS Federal prescribers to register with State PDMP to request reports for new patients, and when pre-scribing opiates for acute pain (>7 days of treatment) and chronic pain.
 - ► Establishes requirement for IHS Pharmacies to report dispensing data and conduct PDMP queries prior to dispensing outside prescriptions.



CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016







Clinician Supports

- IHS Websites
 - Pain Management www.ihs.gov/painmanagement
 - Opioid Dependence Management <u>www.ihs.gov/odm</u>

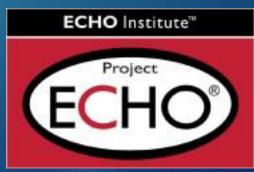




Clinician Supports

- ► IHS Chronic Pain and Opioid Management TeleECHO Clinic
 - Weekly video conference
 - Allows front-line clinicians to consult with experts in:
 - ▶ Pain management
 - Addictions
 - ▶ Behavioral Health
 - ▶ Weekly format rotating to noon hour for each time zone.





Safe Opioid Prescribing Training

- ► IHS Essential Training on Pain and Addiction (ETPA)
 - ► IHS specific training developed with cooperation by the University of New Mexico.
 - ▶ Web-based live trainings (5 hour course) conducted since Jan. 2015.
- ► IHS Special General Memorandum 2016-05: Mandatory Training for Federal Prescribers of Controlled Substance Medications
 - ► All IHS Federal prescribers of controlled substances are required to complete EPTA training.
 - ▶ By the end of 2016, 2931 participants had completed the ETPA course.
 - ▶ 1296 IHS Federal controlled substance prescribers (96%).



Naloxone—First Responder

- ► IHS-BIA Memorandum of Understanding- December 2015
 - Agreement that IHS Federal pharmacies will provide naloxone and training on its use to local BIA Tribal Police for use by First Responders.
 - **Total BIA Officers Trained:**
- ► IHS pharmacists have developed a training curriculum and toolkit.
 - ► Training video developed:
 - https://www.youtube.com/watch?v=KcjF9Iw0iuw

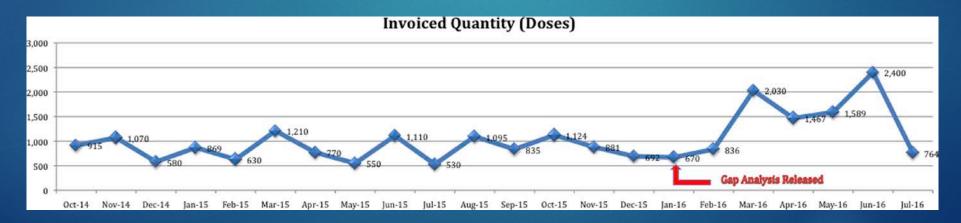




Naloxone—Co-Prescribing

- Co-prescribing grand rounds conducted February 17, 2017
 - https://ihs.adobeconnect.com/p727st8p3lj/

- Pharmacy-based model collaborative practice program developed
 - www.ihs.gov/odm.resources







Medication Assisted Treatment (MAT)

- Medication-assisted treatment is treatment for addiction that includes:
 - ▶ The use of medicine
 - Counseling
 - Support systems
- Treatment that includes medication is often the best choice for opioid addiction.
- ▶ If a person is addicted, medication allows him or her to regain a normal state of mind, free of drug-induced highs and lows.



Medication Assisted Treatment (MAT)

- Office-Based Opioid Treatment Training
 - ► Live web-based training sponsored by American Osteopathic Academy of Addiction Medicine and SAMHSA.
 - ▶ Provides 8 hours needed to obtain waiver to prescribe buprenorphine in an office-based setting:
 - ► Webinar training (4.25 hrs)- 3 modules
 - Online study/exam (3.75 hrs)- 5 modules, 24 questions.
 - ▶ Pain Skills Intensive Training- Albuquerque, NM- March 2017
 - ► Included optional 4 hour MAT training.
 - Duplicate training planned for Nov. 2017 in Portland Area.

Questions

Stephen.Rudd@ihs.gov (Chair)
Cynthia.Gunderson@ihs.gov (Vice Chair)
Brandon.Anderson@ihs.gov (Secretary)

- Prescriber Support: Dr Chris Fore
- MAT: CDR Kailee Fretland
- ► Harm Reduction: CDR Hillary Duvivier
- Perinatal Substance Use: Dr Jonathan Gilbert; CDR Ted Hall
- Metrics: Dr Tamara James
- ► Technical Assistance: CDR Tyler Lannoye
- Website & Communications: Kristin Allmaras
- Executive Leadership Committee: Dr Michael Toedt, Dr Beverly Cotton, CAPT Kevin Brooks

End of Presentation



The Impact of the Opioid Crisis in Rural America

Federal Office of Rural Health Policy
Health Resources and Services Administration

Michael Fallahkhair & Michael Blodgett





Federal Office of Rural Health Policy

U.S. Department of Health and Human Services

Quick Background

- Part of HRSA & DHHS
- "Voice for Rural"
- Policy and Research Role
- Review HHS Regulations
- Administer Grant Programs
- Technical Assistance

Mission

Collaborate with rural communities and partners to support programs and shape policy that will improve health in rural America.



Federal Office of Rural Health Policy

U.S. Department of Health and Human Services

Office Structure



Community-Based Programs



Policy & Research



Hospital State Programs



Telehealth Programs



Federal Office of Rural Health Policy

U.S. Department of Health and Human Services

- Sec. 330a of Public Health Service Act (PHS)
 - Rural Health Outreach Services
 - Rural Health Network Development
 - Rural Network Development Planning
 - Small Healthcare Provider Quality Improvement
 - Delta States Network
 - Rural Network Allied Health Training
 - Rural Health Care Coordination Network Partnership
 - Rural Benefits Counseling
 - Rural Health Opioid Program
- Black Lung Clinics Program & Black Lung Center of Excellence
- Radiation Exposure Screening Education

Community Based Programs









Rural Trends

Trend 1

 Opioid-related overdose deaths have increased over the past 15 years in both rural and urban, with exponential increases in rural areas from 2015-2016

Trend 2

 Rural states are more likely to have higher rates of overdose death, particularly from prescription opiate overdose

Trend 3

 Rural men may be using more, but rural women are dying more





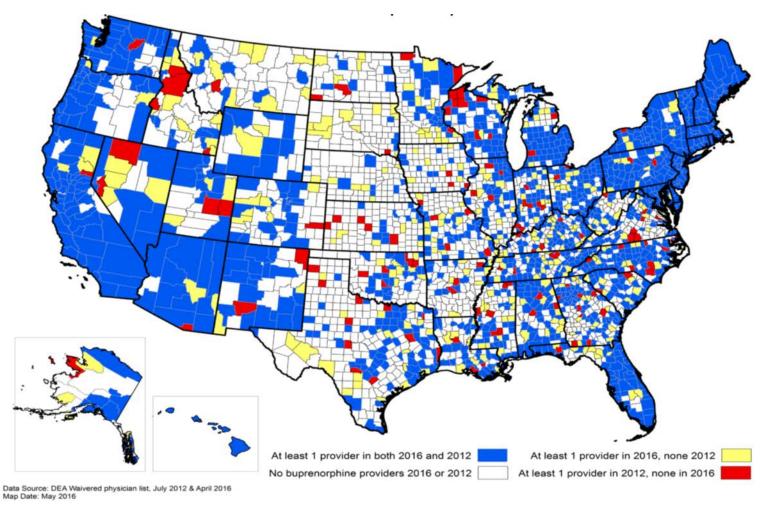
Buprenorphine

- 2.2% of US physicians had obtained DATA waivers to prescribe buprenorphine
 - 41.6% of waivered physicians are psychiatrists
 - 3% of all primary care physicians have obtained waivers
- Barriers exist for both providers and patients
- Nationwide treatment need and capacity
 - Assuming 100% capacity, 1 million patients
 - Assuming 57% capacity, 1.3 to 1.4 million patients





Geographic Distribution of Physicians with DATA Waivers









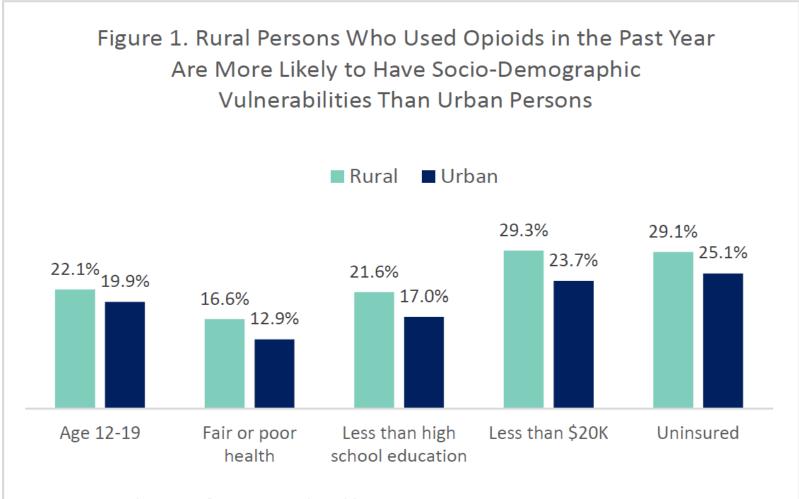
Methadone

- Opioid Treatment Programs (OTPs) provide methadone treatment
 - 1,484 OTPs (2017) 1,067 OTPs (2003)
- 82% of OTPs nationally reported operating at 80% or greater capacity
- In 2012, 3.5 times as many patients could be treated with buprenorphine as were receiving methadone in OTPs
- OTPs concentrated in urban areas





Rural Socio-Demographic Vulnerabilities





Data: National Survey of Drug Use and Health, 2008-13.

Residence differences significant at p<.001



Rural-Specific Challenges

- Significant variations in opioid prescribing patterns due to inconsistent use of evidence-based prescribing guidelines and limited access to specialty pain management support
- Continued stigmatization of individuals with OUD in many rural communities
- Emphasis on criminalizing individuals with OUD rather than treating them as chronic diseases
- Limited access to specialty substance use and mental health services in rural areas
- Difficulties recruiting and retaining an adequate prevention, treatment, and recovery workforce
- Impediments to inter-agency collaboration on opioid issues in poorly-resourced rural areas.





Promising Strategies in Rural

- Engaging the community to address opioid issues, including broad-based coalitions
- Encouraging prescribers to adopt evidence-based opioid prescribing guidelines
- Implementing hospital emergency department protocols to manage access to opioids
- Expanding access to MAT through primary care-based models
- Supporting community buprenorphine prescribers through hub and spoke and telehealth models
- Developing models to support recovery and reduce relapse in rural communities





Reducing Substance Abuse - Efforts by HRSA

- Substance Abuse Service Expansion (BPHC)
 - In March 2016 HRSA awarded 100 million to nearly 300 health center grantees for the expansion of substance abuse services
- Access Increases in Mental Health and Substance Abuse Services (BPHC)
 - Supplemental funding to expand access to mental health services, and substance abuse services focusing on the treatment, prevention, and awareness of opioid abuse in FQHCs.
- Substance Abuse Warmline (BPHC)
 - Peer-to-peer telephone consultation, focusing on substance use evaluation and management for primary care clinicians
- Project ECHO Collaborative (BPHC)
 - Bi-weekly web-based training in opioid addiction treatment serving FQHCs, with a focus on clinics receiving SASE awards



Reducing Substance Abuse - Efforts by HRSA

Health Care for the Homeless Demonstration Project (HAB)

• 5-year initiative that supports innovative practices to increase entry and retention into HIV care, as well as support services for patients who are homeless or unstably housed and those who are living with mentally illness or substance use disorders

Behavioral Health Workforce Education and Training Program (BHW)

• Supports the training of the behavioral workforce to ensure an adequate supply of professionals across the country, and in particular, within underserved and rural communities

Prevention of Opioid Misuse in Women (OWH)

• 12 cooperative agreements to prevent the misuse of opioids by women across the lifespan

Federal Home Visiting Program (MCHB)

• This program gives pregnant women and families, particularly those considered at-risk, necessary resources and skills to raise children who are physically, socially, and emotionally healthy and ready to learn



Federal Office of Rural Health Policy Programs

- Rural Opioid Overdose Reversal Grant Program (ROOR)
- Rural Health Opioid Program (RHOP)
- Substance Use Disorder Telehealth Network Grant Program (SUD-TNGP)
- Rural Health Care Services Outreach Program (Outreach)





Rural Opioid Overdose Reversal Grant Program (ROOR)

FY15-16 Pilot Program

- Total Investment: \$1.8 Million (18 awards at \$100,000/year)
- Support rural community partnerships comprised of local emergency responders and other entities involved in the prevention and treatment of opioid overdoses
- Increasing access to naloxone in rural communities

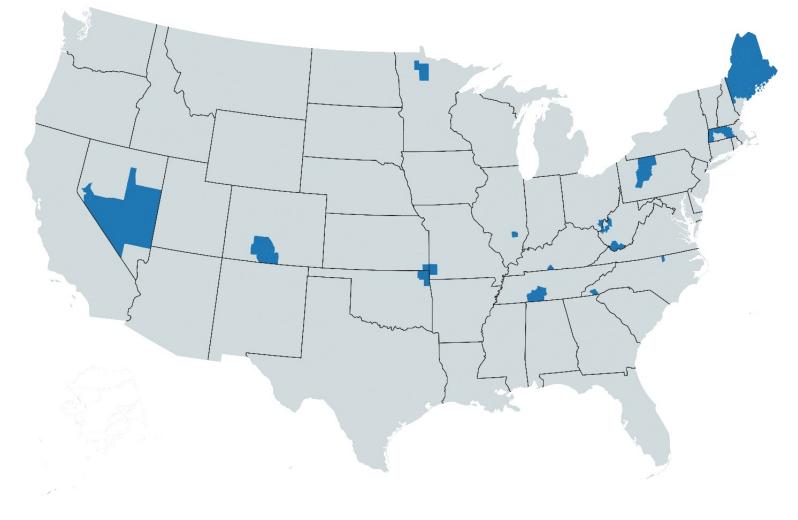
Objectives

- Increase the availability of naloxone through purchase and strategic placement
- Train individuals to recognize the signs of opioid overdose and administer naloxone
- Referral to substance abuse treatment centers where care coordination can be provided by team of providers
- Demonstrate improved and measureable health outcomes, including reducing opioid overdose morbidity and mortality in rural areas





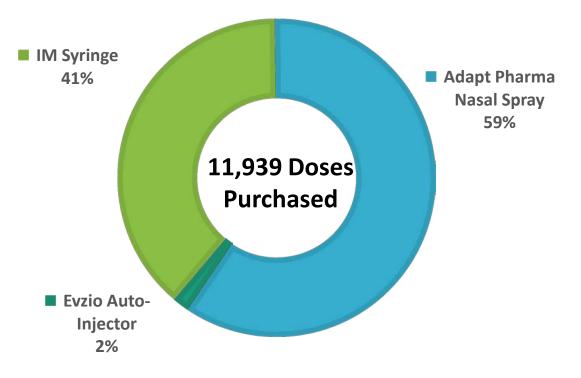
Rural Opioid Overdose Reversal Grant Program Service Areas



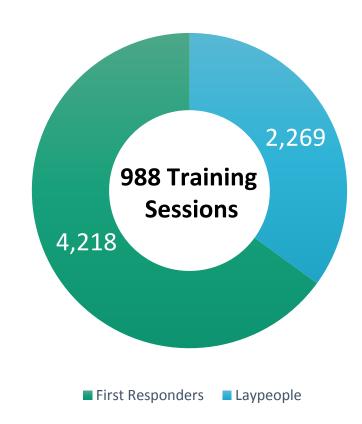


Rural Opioid Overdose Reversal Grant Program Results

NALOXONE DOSES PURCHASED BY TYPE



INDIVIDUALS TRAINED TO RECOGNIZE AN OVERDOSE AND ADMINISTER NALOXONE



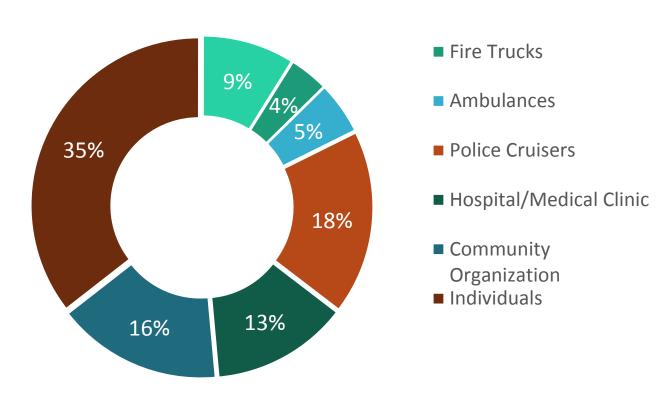




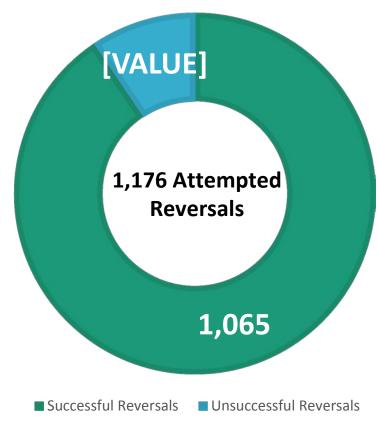


Rural Opioid Overdose Reversal Grant Program Results

NALOXONE DISTRIBUTION POINTS



SUCCESSFUL/UNSUCCESSFUL REPORTED REVERSALS





Rural Health Opioid Program (RHOP)

FY17-20 Pilot Program

- Total Investment: \$2.5 Million (10 awards up to \$250,000/year)
- Support rural community partnerships comprised of local health care providers, emergency responders and other community organizations involved in the treatment and recovery of opioid use disorder

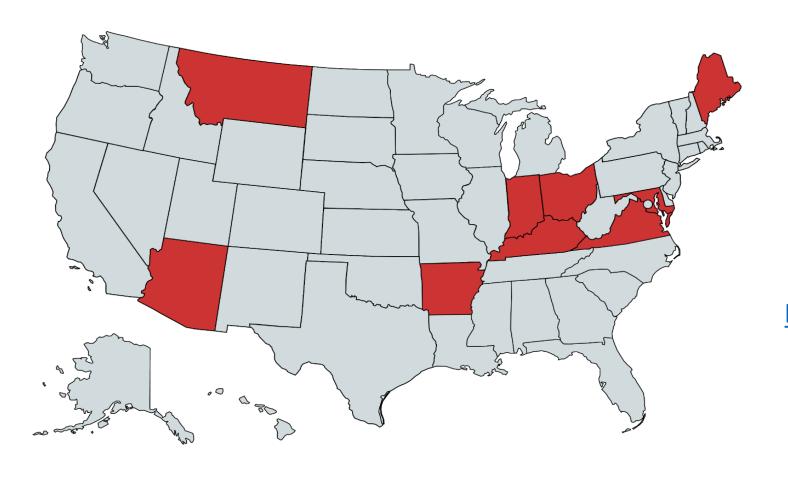
Objectives

- Identify individuals at-risk of overdose and guide them towards recovery by providing outreach and education on locally available treatment options and support services
- Educate community members on opioid use disorder, treatment options and methods for preparing and referring individuals with OUD to treatment
- Implement care coordination practices to organize patient care activities
- Support individuals in recovery by establishing new or enhancing existing behavioral counselling and peer support activities





Rural Health Opioid Program - State Representation



FY17 Project Abstracts





Rural Health Opioid Program - Project Activities Snapshot

- Providing trainings to healthcare facility staff on SBIRT
- Implementing case management services
- Utilizing telehealth for behavioral counselling and support services
- Introducing the "Hub and Spoke" model to proposed service areas
- Providing overdose education and naloxone distribution programs
- Expanding withdrawal monitoring and support services
- Educating the community on addiction, local opioid issues and methods of treatment
- Utilizing Peer Recovery Coaches to support individuals in treatment and recovery



Substance Use Disorder Telehealth Network Grant Program (SUD-TNGP)

FY17-20 Pilot Program

- Total Investment: \$750,000 (3 awards up to \$250,000/year)
- Demonstrate how telehealth programs and networks can improve access to health care services, particularly substance abuse treatment services, in rural, frontier, and underserved communities.

Objectives

- Provide substance use disorder treatment using telehealth technology to rural communities particularly small rural hospitals with high rates of poverty, unemployment, and substance use
- Provide health care services using telehealth technology to address comorbid conditions (e.g. mental health, congestive heart failure, cancer, stroke, chronic respiratory disease and/or diabetes)
- Improve and expand health care provider training related to substance use disorders
- Expand and improve the quality of health information available to heath care providers as well as
 patients and their families

Rural Health Care Services Outreach Program (Outreach)

FY18-21

- Total Investment: \$5 Million (25 awards up to \$200,000)
- Expand the delivery of health care services in rural areas

Objectives

- Expand the delivery of health care services to include new and enhanced services exclusively in rural communities
- Deliver health care services through a strong consortium, in which every consortium member organization is actively involved and engaged in the planning and delivery of services
- Utilize and/or adapt an evidence-based or promising practice model(s) in the delivery of health care services
- Improve population health, and demonstrate health outcomes and sustainability



Application Due Date: December 6, 2017

Notice of Funding Opportunity now available at Grants.gov!



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End of Presentation

