

# OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH



## THE OPIOID EPIDEMIC AND EMERGING PUBLIC HEALTH POLICY PRIORITIES

PRESENTED TO THE  
AMA NATIONAL ADVOCACY CONFERENCE  
February 13, 2019

ADMIRAL BRETT P. GIROIR, M.D.  
Assistant Secretary for Health and Senior Advisor for Opioid Policy



# THE STATE OF OPIOID MISUSE IN AMERICA (2017)

**11.4 million**  
people misused opioids  
in the past year

- 11.1 million misused pain relievers
- 886,000 used heroin
- 562,000 both misused pain relievers and heroin

**2.1 million**  
people had an opioid  
use disorder

- 1.7 million people with a prescription pain reliever use disorder
- 652,000 people with a heroin use disorder
- 252,000 had both pain reliever and heroin use disorders

**53.1%**

obtained the last  
pain reliever they  
misused from a  
friend or relative

**36%**

from a prescription  
from a healthcare  
provider

**Main reasons for opioid misuse: Pain 62.6%**

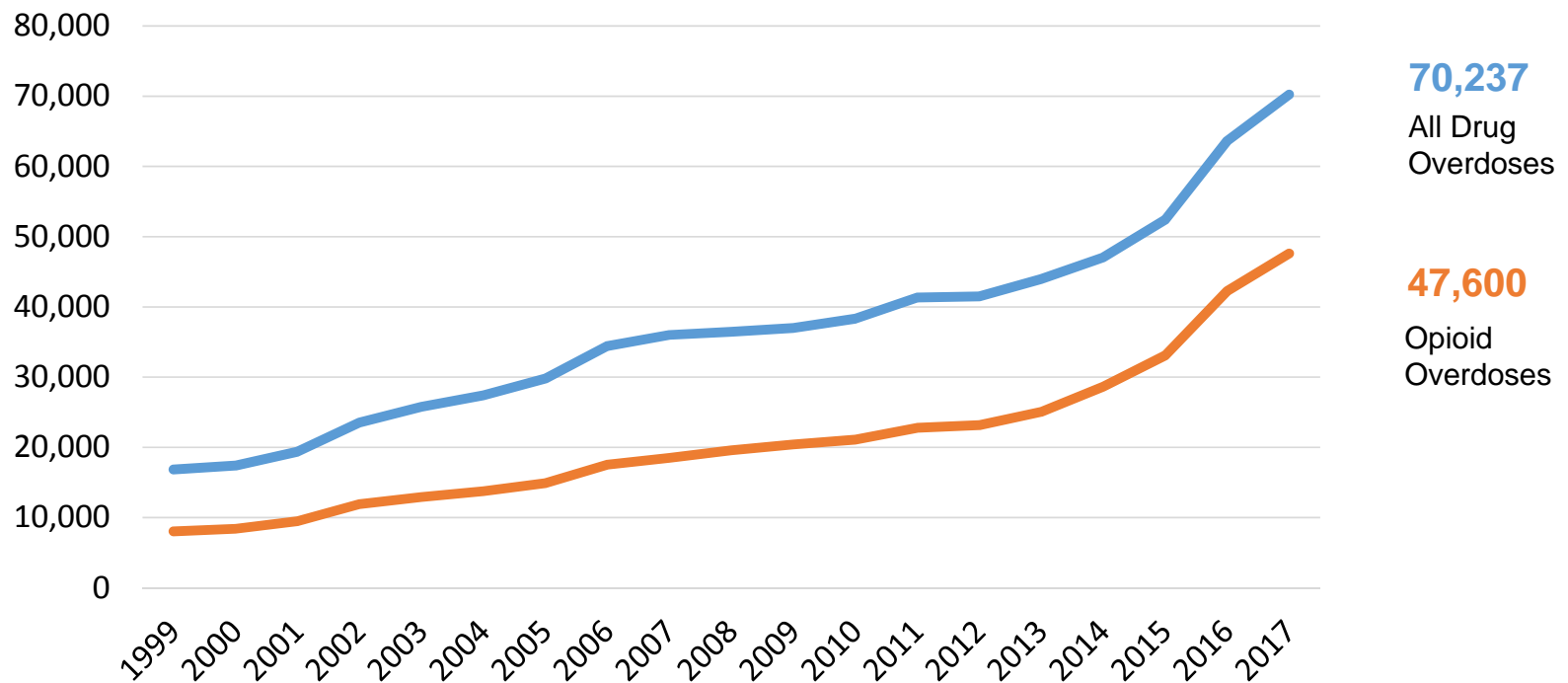


OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

NSDUH, 2017 Data; published Sept. 2018

# U.S. DRUG OVERDOSE DEATHS

THE MOST CRITICAL PUBLIC HEALTH CHALLENGE OF OUR TIME



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

SOURCE: NCHS, National Vital Statics System, Mortality

# OVERDOSE MORTALITY BY CLASS OF DRUG

ADAPTED FROM CDC STATISTICS, JANUARY 2019

	HEROIN	NAT & SEMI – SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS	COCAINE	PSYCHO- STIMULANTS
<b>JUNE 2017 *</b>	16,622	15,546	3,357	26,057	13,367	9,446
<b>JUNE 2018 *</b>	15,283	13,929	3,283	31,551	15,095	11,741
<b>Change</b>	<b>-8.06%</b>	<b>-10.04%</b>	<b>-2.20%</b>	<b>21.08%</b>	<b>12.93%</b>	<b>24.30%</b>

<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

**>70% of Cocaine Deaths also have Opioids Detected**



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

- Number of predicted deaths for the 12 months ending in June of the indicated year

# SHOCKING LEVELS OF ILLICIT DRUG SMUGGLING



## Feds make largest fentanyl bust in U.S. history

Jan. 31, 2019



- CBP officers seized:
  - **254 pounds of fentanyl** in a floor compartment of a truck trailer loaded with cucumbers
  - **395 pounds of methamphetamine**
- **Fentanyl sufficient to kill >50 million people**

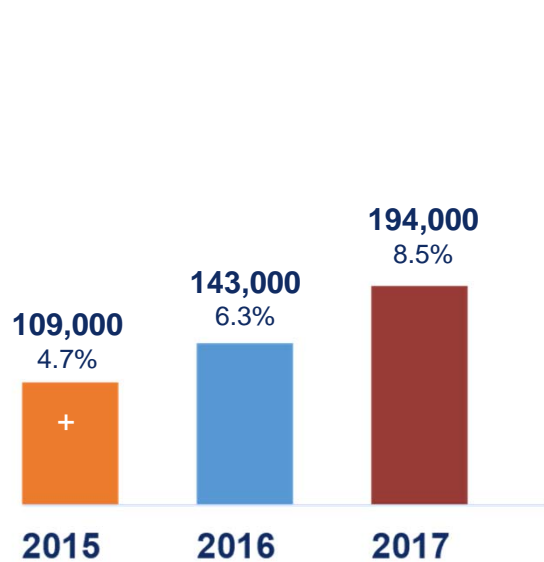
CBP estimates the fentanyl street value at \$3.5 million



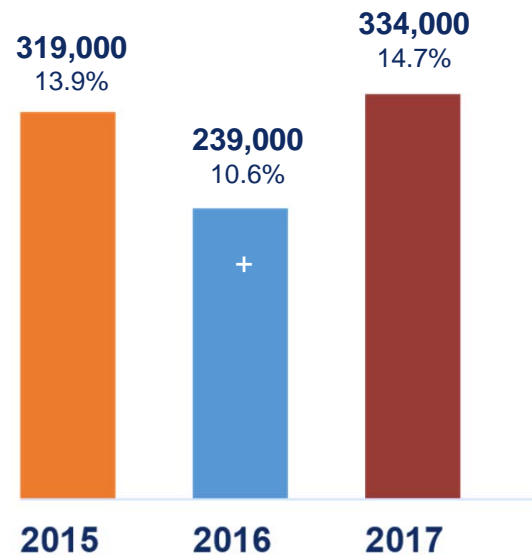
OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# LAST MONTH SUBSTANCE USE AMONG PREGNANT WOMEN

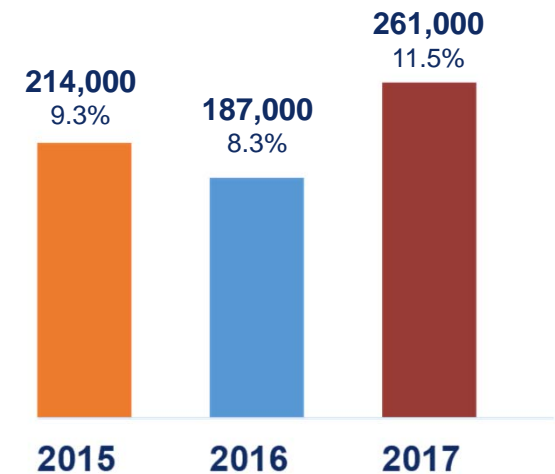
## ILLICIT DRUGS



## TOBACCO PRODUCTS



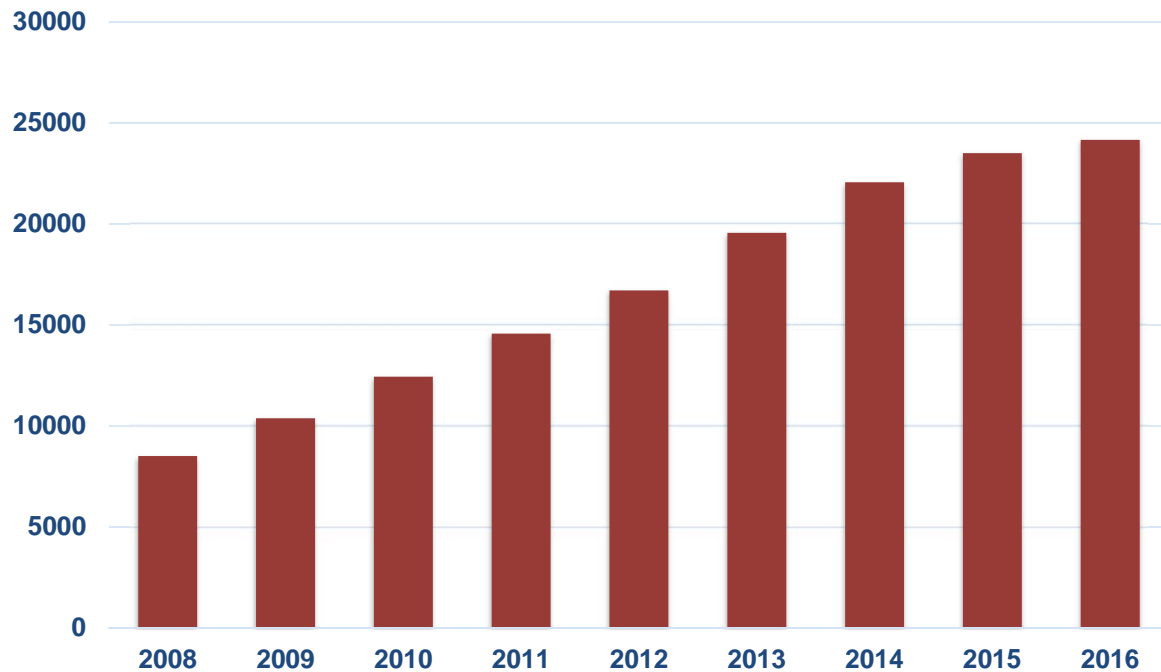
## ALCOHOL



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

NSDUH, 2017 Data; published Sept. 2018

# NEWBORN VICTIMS OF THE OPIOID EPIDEMIC



Source: AHRQ HCUP State Inpatient Databases

## Outcomes in the fetus

- Growth restriction
- Prematurity
- Death

## Outcomes in the Newborn

- Low birthweight
- Small head circumference
- Neonatal abstinence syndrome

## Outcomes in the Child

- Developmental disorders



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

McQueen, NEJM 2016

# GASTROSCHISIS LINK TO OPIOID PRESCRIPTION RATES

- 2011-2015: 2.5 per 10,000 live births
- 2006-2010: 10% increase
- Ecologic analysis: higher prevalence of gastroschisis in areas where opioid prescription rates were higher
- Supports epidemiologic data suggesting link between gastroschisis and opioid use during pregnancy



*Graphic Courtesy of CDC*

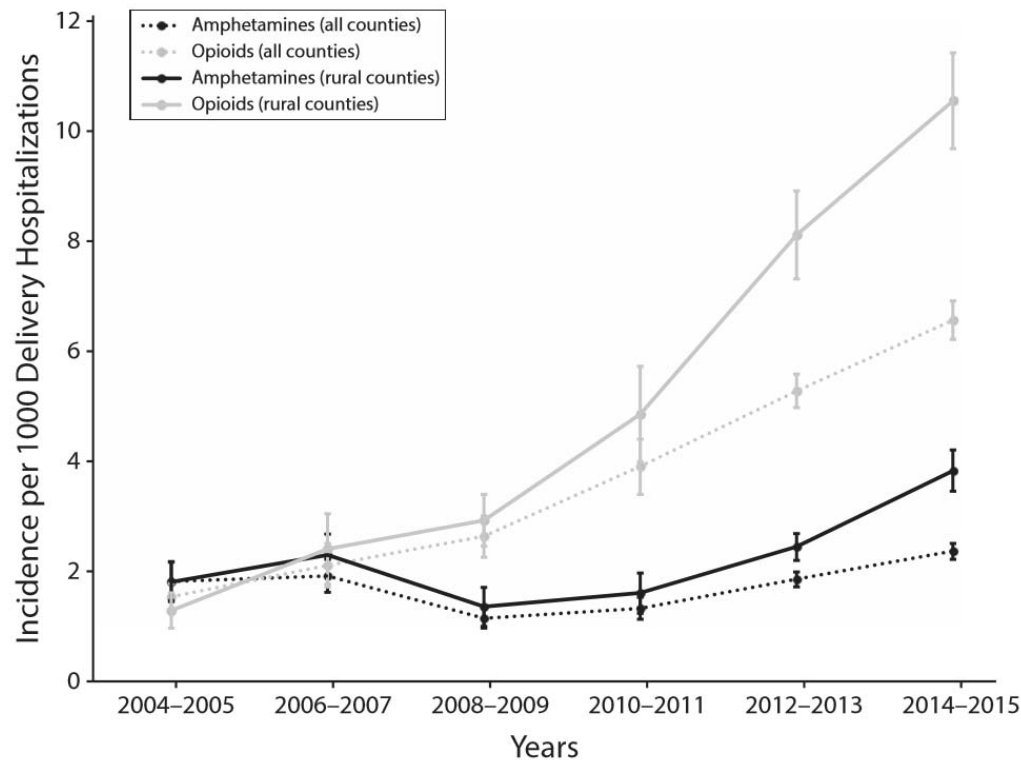


OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

Short et al, MMWR, Jan 18, 2019



# INCIDENCE OF OPIOID AND AMPHETAMINE RELATED DELIVERIES (US, 2004-2015)



- Increased disproportionately across rural compared with urban counties in 3 of 4 census regions between 2008 to 2009 and 2014 to 2015
- Amphetamine-related deliveries were associated with higher incidence of **preeclampsia, preterm delivery, and severe maternal morbidity and mortality**

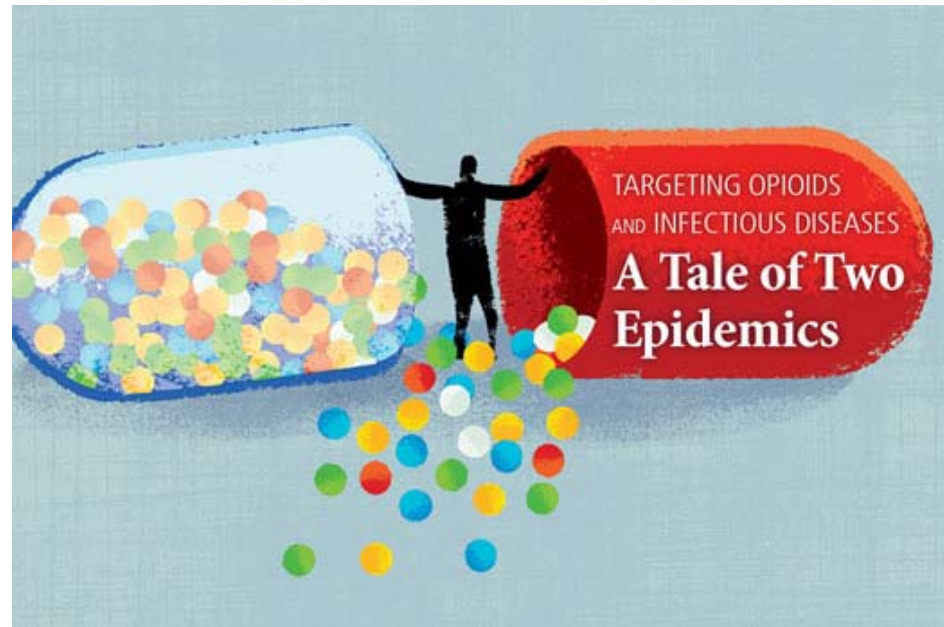


OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

*Admon et al, AJPH, 2019;109:148-154.*

# INFECTIOUS CONSEQUENCES OF THE OPIOID EPIDEMIC

- **HIV**
- **Hepatitis C**
- Hepatitis B
- Endocarditis
- Skin, bone, and joint infections



**National Academies Workshop**  
Sponsored by OASH, Report July 2018



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# HHS 5-POINT STRATEGY TO COMBAT THE OPIOIDS CRISIS



**Better** addiction prevention, treatment, and recovery services



**Better** data



**Better** pain management



**Better** targeting of overdose reversing drugs



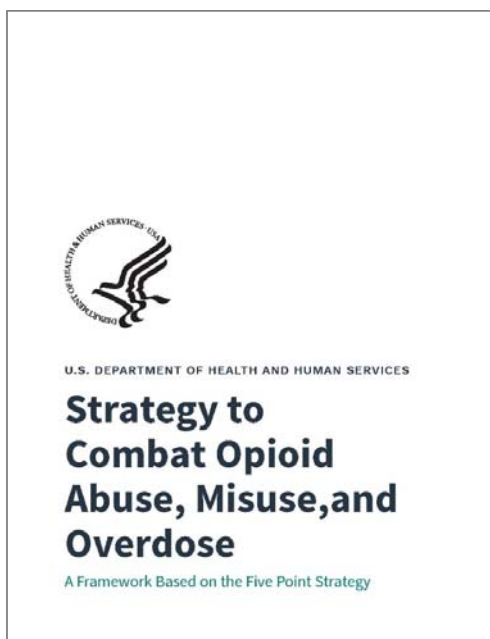
**Better** research

<https://www.hhs.gov/opioids/>



# HHS OPIOIDS OVERALL STRATEGY UPDATE

RELEASED SEPTEMBER 17, 2018



“The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy.”

Secretary Alex Azar



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

<https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf>

# WHAT IS EVIDENCE-BASED TREATMENT?

- **FDA-approved Medication (MAT)**

- Naltrexone: once a month injectable medication, blocks effects of opioids (Any prescriber)
- Methadone: long acting, once-daily, opioid from specially licensed programs (OTP programs only)
- Buprenorphine/naloxone: long acting, once daily/once monthly, opioid from doctor's offices (Waivered prescribers)

- **Psychosocial Therapies**

- Education, coping skills, contingency management and cognitive behavioral therapy

- **Recovery Services - Rebuilding One's Life**

- Social supports to welcome into a healthy community: family, friends, peers, faith-based supports
- Assistance with needs that can impact treatment - recovery housing, transportation and child care
- Employment/Vocational training/education

- **Naloxone**



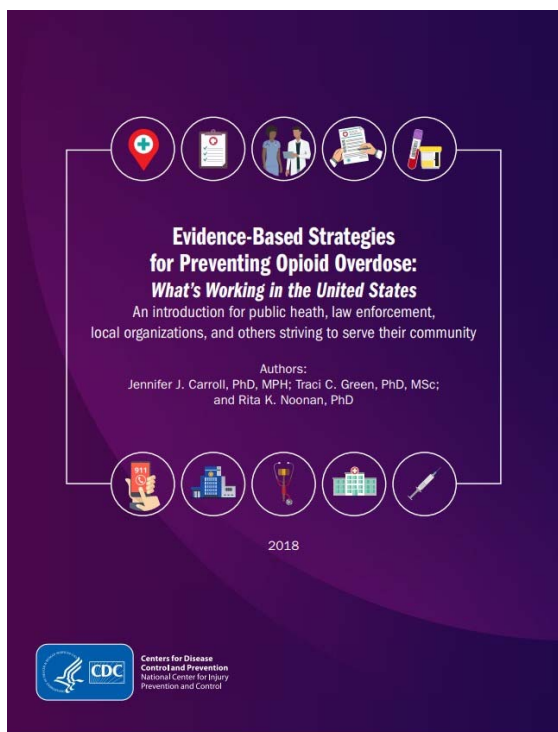
OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# CLINICIANS RECENTLY WAIVERED FOR BUPRENORPHINE PRESCRIBE BELOW THEIR LIMIT OR NOT AT ALL

- **Survey: 4225 clinicians receiving data waiver or increase in authorized patient limit in 2017**
- **Main Findings**
  - Only 75% had prescribed buprenorphine since obtaining the waiver
  - Mean number of patients treated in past month = 26.6
  - **Clinicians prescribing at or near their limit = 13.1%**
- **Barriers to prescribing buprenorphine at or near limit**
  - Lack of patient demand = 19.4%
  - Time constraints in practice = 14.6%
  - Insurance requirements = 13.2%



# NALOXONE: AN ESSENTIAL PART OF THE OPIOIDS SOLUTION



Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present.

## Surgeon General's Advisory on Naloxone and Opioid Overdose

*I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, **knowing how to use naloxone and keeping it within reach can save a life.***

**BE PREPARED. GET NALOXONE. SAVE A LIFE.**



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# BYSTANDER PRESENCE AND NALOXONE

## *Significant Opportunity for Improvement*

11,884 OPIOID DEATHS (CDC ESOOS Data, 11 States, July 2016 – June 2017)

	PRESCRIPTION OPIOIDS (%)	ILLICIT OPIOIDS (%)	PRESCRIPTION AND ILLICIT OPIOIDS (%)
In Category	17.4	58.7	18.5
Previous OD	9.3	15.1	13.5
Bystander present	41.6	44.0	45.0
Bystander naloxone administration	0.8	4.3	4.4



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

Mattson et al., MMWR, Aug 31, 2018



# LACK OF NALOXONE CO-PRESCRIBING TO PATIENTS AT RISK

- **PDX, Inc**

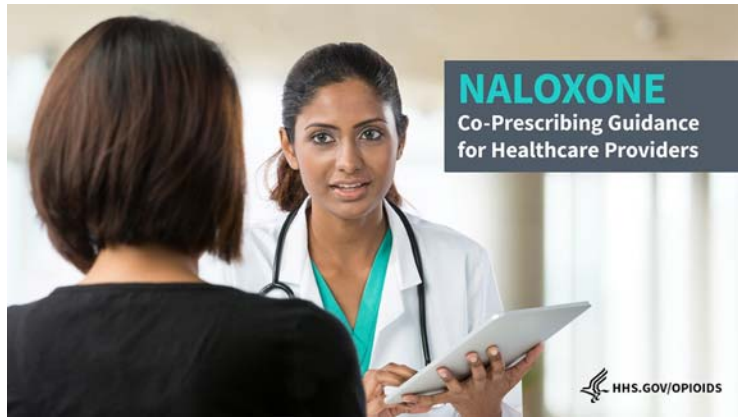
- April – June 2018 (verbal report to HHS)
- 8600 pharmacies nationwide
- For patients on MME > 50, rate of naloxone co-prescribing was 0.3%
- For those prescribed naloxone, 40% never picked up prescription

- **MEDICARE, 2017**

- MME > 50: rate of naloxone co-filling was 1.3%
  - MME = 90 – 120: rate of naloxone co-filling was 1.6%
  - MME > 120: rate of naloxone co-filling was 5.2%
- ✓ Primary drivers of co-prescribing are states with mandatory co-prescription laws



# HHS RECOMMENDATION: PRESCRIBE NALOXONE TO ALL PATIENTS AT HIGH RISK OF OPIOID OVERDOSE



- Reinforces and expands upon prior CDC guidelines
- Clinicians should also educate patients and those who are likely to respond to an overdose, including family members and friends, on when and how to use naloxone in its variety of forms

December 19, 2018  
Assistant Secretary for Health Guidance

**Prescribe or co-prescribe naloxone to individuals at risk for opioid overdose including individuals who**

- are on relatively high doses of opioids
- take other medications which enhance opioid complications
- have underlying health conditions



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

<https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf>

# ACHIEVING RESULTS IN COMBATING THE OPIOID EPIDEMIC

## PROGRESS (JANUARY 2017 – NOVEMBER 2018)

- The total morphine milligram equivalents dispensed monthly by retail and mail-order pharmacies ***declined by 25.6%***.
- Number of unique patients receiving buprenorphine monthly from retail pharmacies ***increased by 21.9%***.
- The number of naltrexone prescriptions per month from retail and mail pharmacies has ***increased more than 46.9%***.
- Naloxone prescriptions dispensed monthly by retail and mail-order pharmacies have ***increased by 338%***.



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

Source: IQVIA National Prescription Audit. Data Retrieved on December 13, 2018.

Source: IQVIA Total Patient Tracker. Data Retrieved on December 18, 2018.

# ACHIEVING RESULTS IN COMBATING THE OPIOID EPIDEMIC

## PROGRESS (2015 to 2017)

- The number of individuals who misused pain relievers *decreased from 12.5 million to 11.1 million.*
- The number of individuals with pain reliever use disorder *decreased from 2.0 million to 1.7 million.*

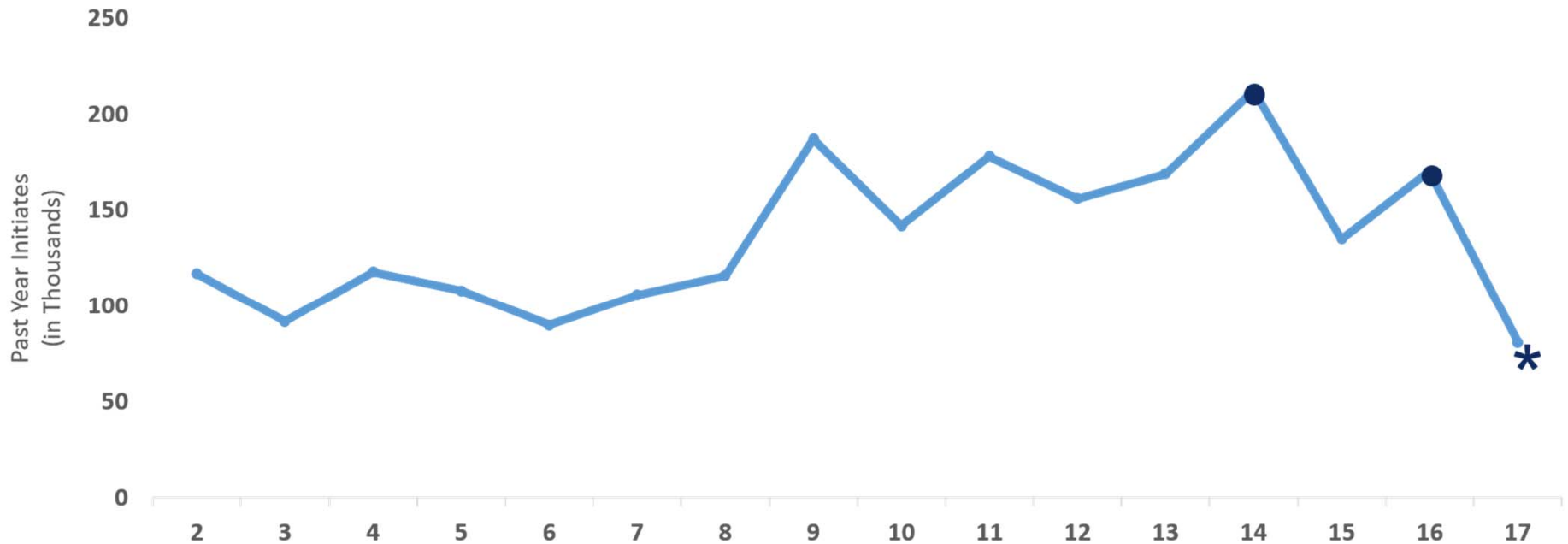


OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# NATIONAL SURVEY ON DRUG USE AND HEALTH, 2017

## FIRST TIME HEROIN USERS DROPPED BY >60% (2016-2017)

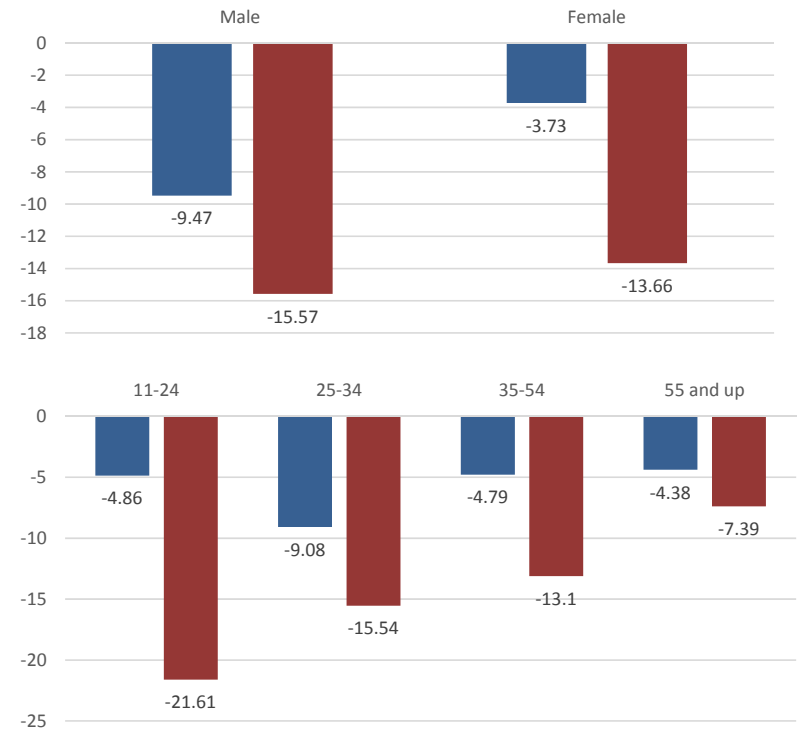
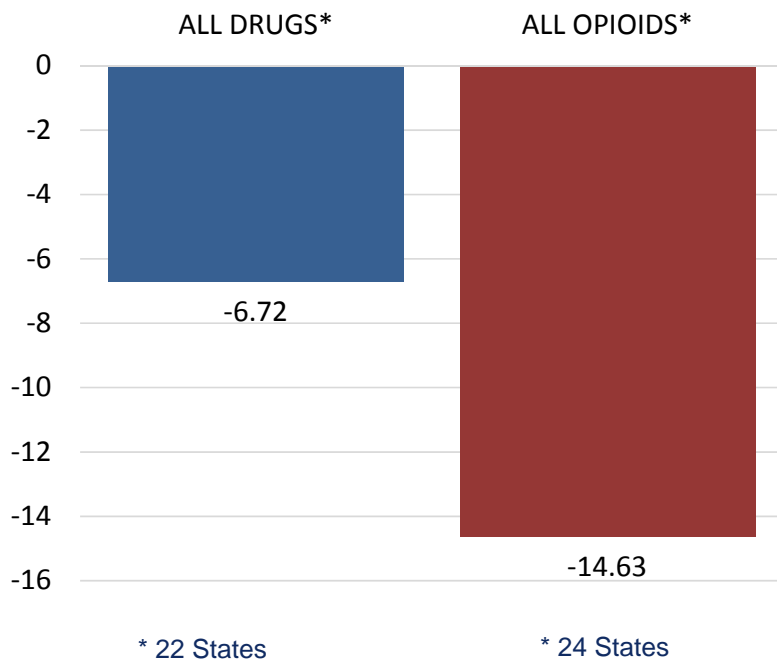
*Past Year Heroin Initiates among People Aged 12 or Older (in thousands): 2002-2017*



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

NSDUH, 2017 Data; published Sept. 2018

# ED VISITS FOR SUSPECTED DRUG OVERDOSE (% CHANGE) Q2 2017 – Q2 2018

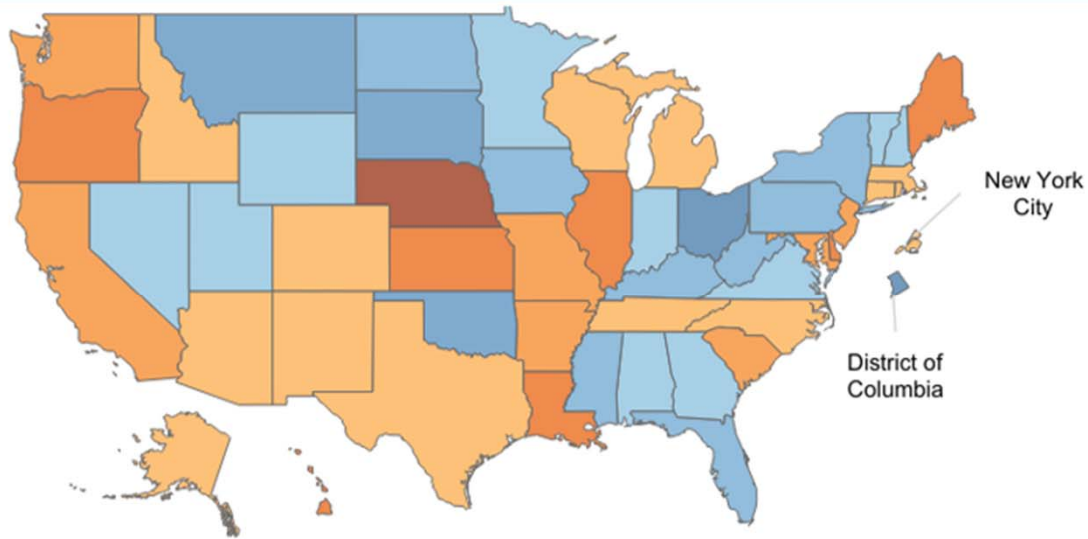


OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

Source: CDC Enhanced State Opioid Overdose Surveillance Program (ESOOS)

# OVERDOSE MORTALITY (PREDICTED): CDC JANUARY 2019

Figure 1b. Percent Change in Predicted 12 Month-ending Count of Drug Overdose Deaths, by Jurisdiction: June 2017 to June 2018



Select predicted or reported number of deaths

- Predicted
- Reported

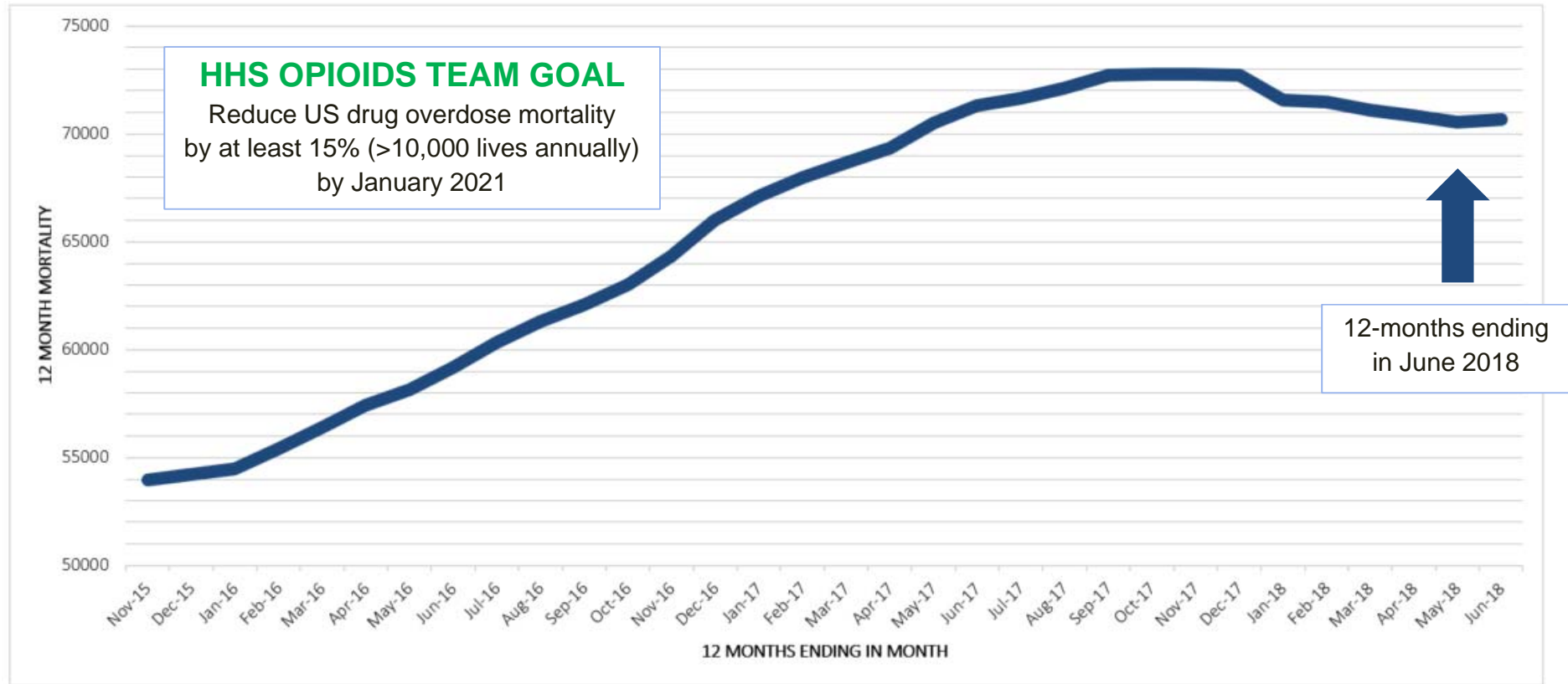
Percent Change for United States

-0.9 ▼



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# 12 MONTH OVERDOSE MORTALITY: CDC JUNE 2018



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH



# IMPLEMENT SUPPORT ACT (1)

## SUPPORT FOR PATIENTS AND COMMUNITIES ACT

ENABLES HHS TO BUILD AND EXPAND PROGRAMS THAT ALIGN WITH FIVE-POINT OPIOID STRATEGY

### *Key SUPPORT Act Provisions*

- Improve prescription drug monitoring programs and encourages data sharing between states
- Require the development of evidence-based opioid analgesic prescribing guidelines for treatment of acute pain
- Increase the number of waived healthcare providers that can prescribe or dispense MAT
- Authorize grants to support the development of curriculum that will help healthcare practitioners obtain a waiver to prescribe MAT



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

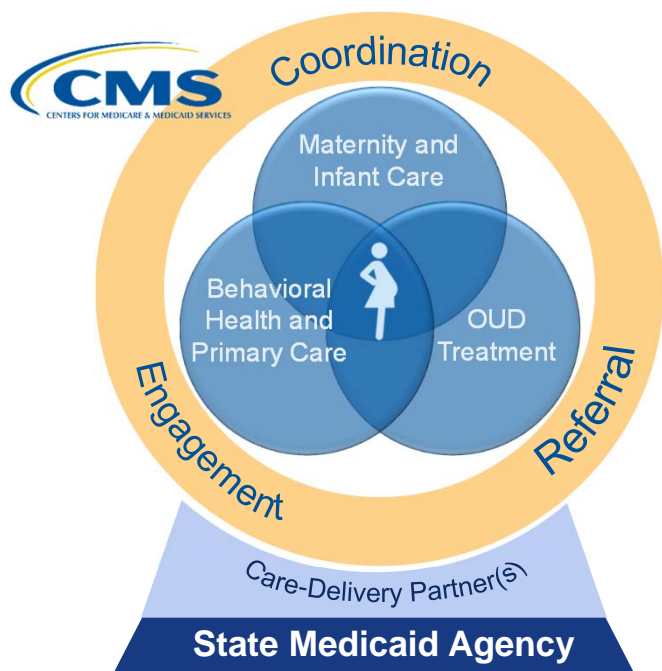
## TRANSFORM TO A SUSTAINABLE MODEL (2)

Transitioning from a “crisis framework” into an integrated, sustainable, predictable, and resilient public health system for preventing and treating substance use and other behavioral health disorders.



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# MATERNAL OPIOID MISUSE (MOM) MODEL



The MOM model is a *patient-centered, service-delivery model*, which aims to *improve the quality of care* and *reduce costs* for pregnant and postpartum Medicaid beneficiaries with OUD and their infants through *state-driven care transformation*.

## GOALS

1. **Improve** quality of care and reduce costs
2. **Expand** access to treatment, service-delivery capacity, and infrastructure
3. **Create** sustainable coverage and payment strategies

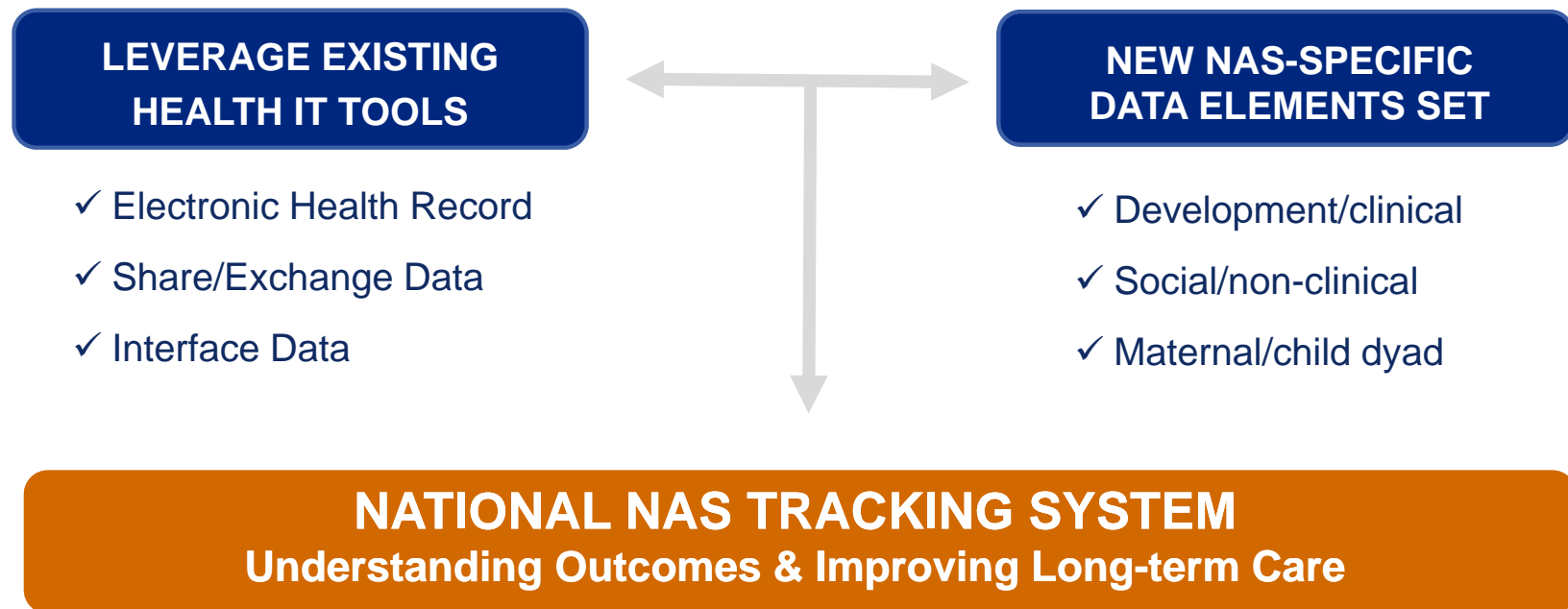
*Notice of funding opportunity release: early 2019 / Application period: Spring 2019  
\$64.5M available for state awardees over five-year model*



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

## RESEARCH AND POLICY ISSUES (3)

DEVELOPING NATIONAL INFRASTRUCTURE TO TRACK, STUDY, AND IMPROVE OUTCOMES OF BABIES WITH NAS



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

## HHS CROSS CUTTING INITIATIVES (4)

INITIATIVE	OBJECTIVE	AGENCIES
<b>HEALing Communities</b>	Reduce overdose fatalities by 40% in 3 years across communities highly affected by the opioid crisis	<b>NIH, SAMHSA, HRSA, ACF, CMS, ASPE, AHRQ, OASH, CDC; DOJ, HUD, Education</b>
<b>Indication-Specific Opioid Prescribing Guidelines</b>	Develop and implement indication-specific best practices for opioid prescribing by 2021	<b>CDC, AHRQ, NIH, OASH, CMS, FDA, IHS, SAMHSA</b>
<b>Opioid Rapid Response Public Health Teams</b>	Establish health “strike teams” to ensure that following a DOJ intervention, 100% of patients have a warm-handoff to a provider.	<b>CDC, Commissioned Corps, Departments of Justice, SAMHSA</b>
<b>Technological Solutions to Prevent Overdose Mortality</b>	Develop and evaluate at least one wearable device that overdose mortality by 2021	<b>BARDA/ASPR, NIH, HHS CTO, DARPA</b>
<b>Transforming the US Healthcare Workforce</b>	Define a novel model(s) for behavioral health care delivery, and increase providers by net 8000 by 2021	<b>HRSA, SAMHSA, CMS, ASPE, IHS, CDC, AHRQ, CDC</b>



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# HIV HAS COST AMERICA TOO MUCH FOR TOO LONG

**700,000**

American lives lost to HIV since 1981

Without intervention and despite substantial progress another

**400,000**

Americans will be newly diagnosed over 10 years despite the available tools to prevent infection

**\$20 billion**

Annual direct health expenditures by U.S. government for HIV prevention and care



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

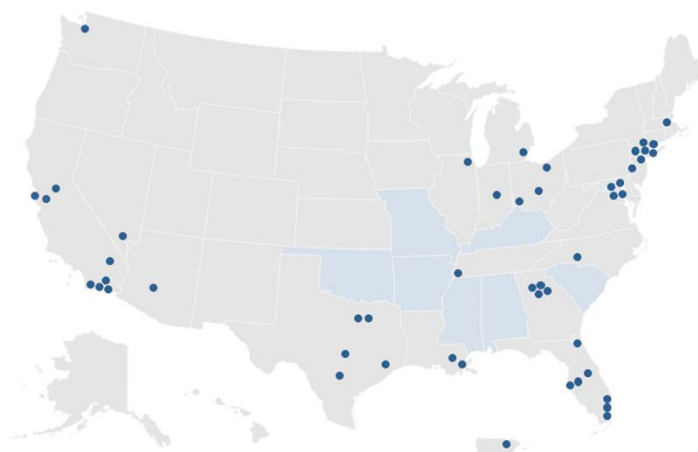
# ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

## GOAL:

**75%**  
reduction in new  
HIV infections  
in 5 years  
and at least  
**90%**  
reduction  
in 10 years.

## FOCUSED EFFORT

- 48 Counties, DC, and San Juan account for 50% of new infections
- 7 States with substantial rural HIV burden



**HRSA**  
Health Resources & Services Administration



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH

# ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

## ACHIEVING THE GOALS

### **DIAGNOSE**

All people with HIV as early as possible after infection

### **TREAT**

The infection rapidly and effectively to achieve sustained viral suppression

### **PROTECT**

People at highest risk of HIV with potent evidence-based interventions

### **RESPOND**

Rapidly and effectively to clusters and outbreaks of new HIV infections

### **HIV HEALTHFORCE**

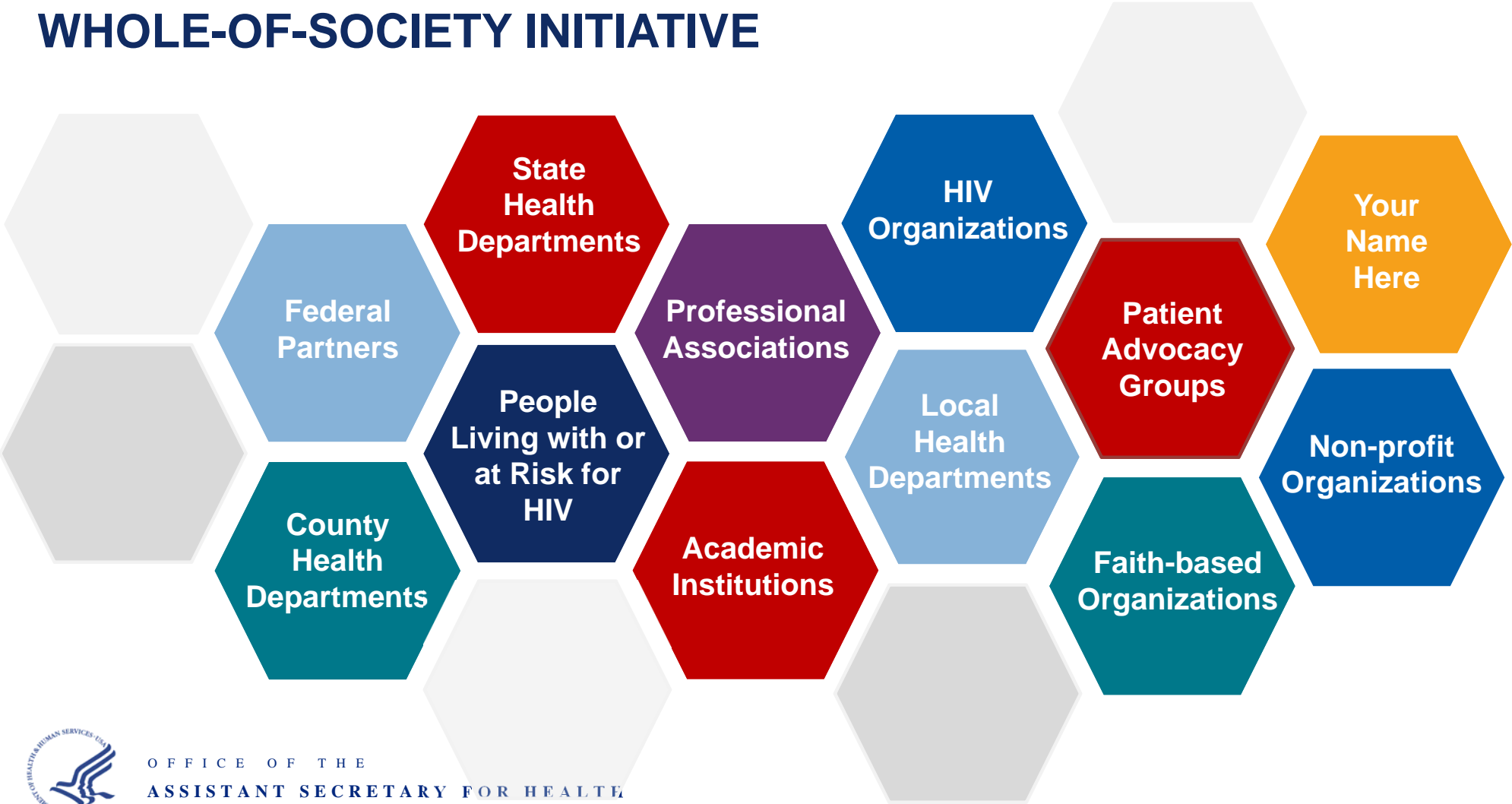
A boots-on-the-ground team that ensures implementation of HIV elimination plans



OFFICE OF THE  
ASSISTANT SECRETARY FOR HEALTH



# WHOLE-OF-SOCIETY INITIATIVE





**BRETT P. GIROIR, M.D.**

ADM, U.S. Public Health Service  
Assistant Secretary for Health,  
Senior Advisor for Opioid Policy

[WWW.HHS.GOV/ASH](http://WWW.HHS.GOV/ASH)

[WWW.USPHS.GOV](http://WWW.USPHS.GOV)

@HHS\_ASH

Brett.Giroir@hhs.gov

Ending  
the  
HIV  
Epidemic

[www.HIV.gov](http://www.HIV.gov)