

Federal Opioids Policy Update



*NIH Interagency Pain Research Coordinating
Committee
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A large collection of various colored pills and capsules scattered on a black background. The pills are in various shapes and sizes, including round tablets, oval capsules, and some with markings. The colors include white, yellow, orange, red, pink, blue, and green. The text "Addressing the Nation's Opioid Abuse Epidemic" is overlaid in the center in a bold, yellow font.

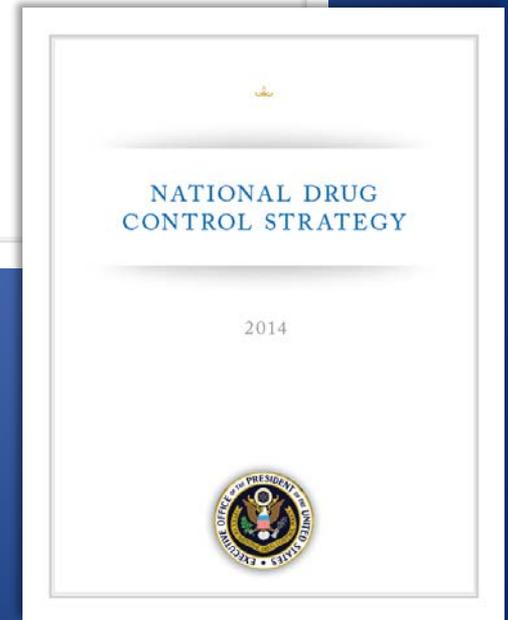
Addressing the Nation's Opioid Abuse Epidemic

Office of National Drug Control Policy

- Component of the Executive Office of the President
- Coordinates drug-control activities and related funding across the Federal Government
- Produces the annual *National Drug Control Strategy*

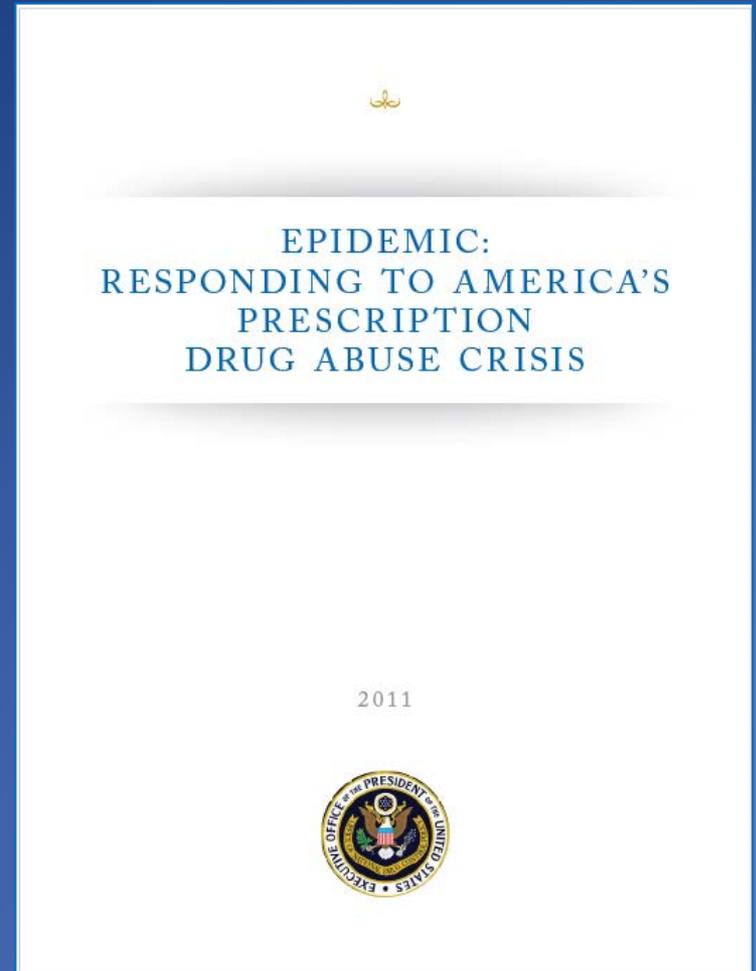
National Drug Control Strategy

- **The U.S. President's science-based plan to reform drug policy:**
 - 1) Prevent drug use before it ever begins through education
 - 2) Expand access to treatment for Americans struggling with addiction
 - 3) Reform our criminal justice system
 - 4) Support Americans in recovery
- **Signature initiatives:**
 - Prescription Drug Abuse
 - Prevention
 - Drugged Driving



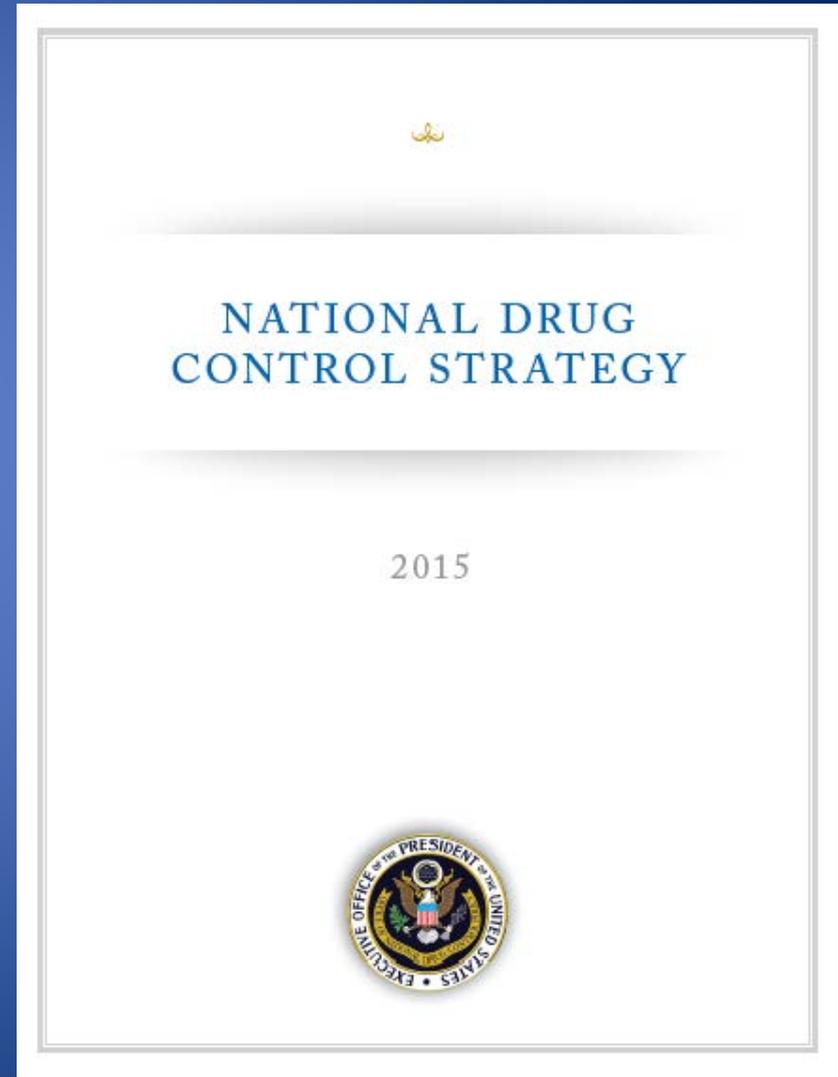
Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal Government
- Four focus areas:
 - 1) Education
 - 2) Prescription Drug Monitoring Programs
 - 3) Proper Disposal of Medication
 - 4) Enforcement

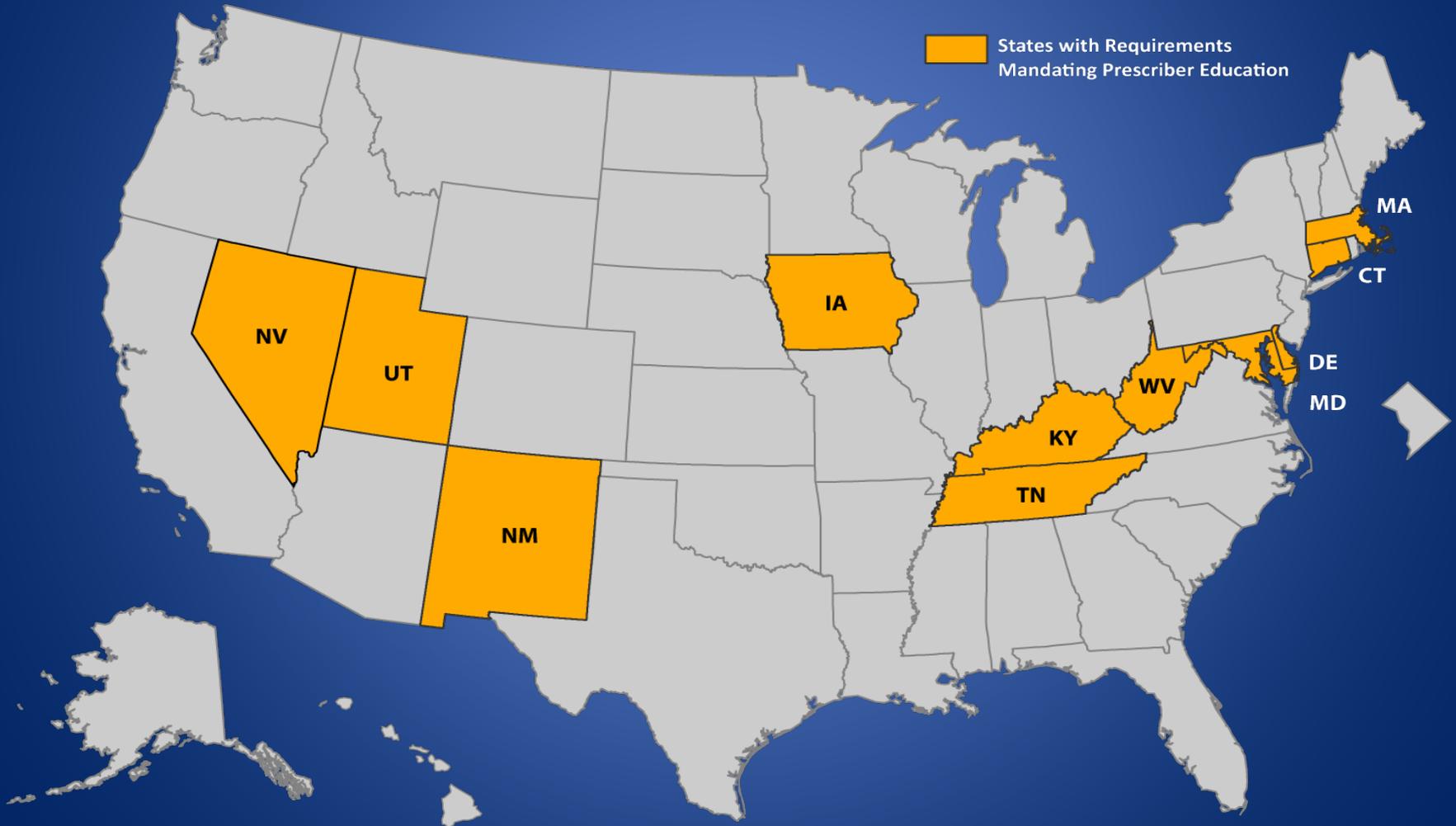


2015 National Drug Control Strategy – Opioids

- Policy Focus: Preventing and Addressing Prescription Drug Misuse and Heroin Use
- Heroin Call-Out Box
- Additional Monitoring Activities: Review and Restriction Program
- Additional Disposal Options: Drug Deactivation Systems
- Overdose Prevention Progress
- Pregnancy



Since 2011, Eleven States Have Instituted Requirements Mandating Prescriber Education



In 2006, only 20 states had prescription drug monitoring programs.



Today, all but one have laws authorizing programs – and 49 are operational and 30 have some data sharing capacity.

Monitoring

Goals

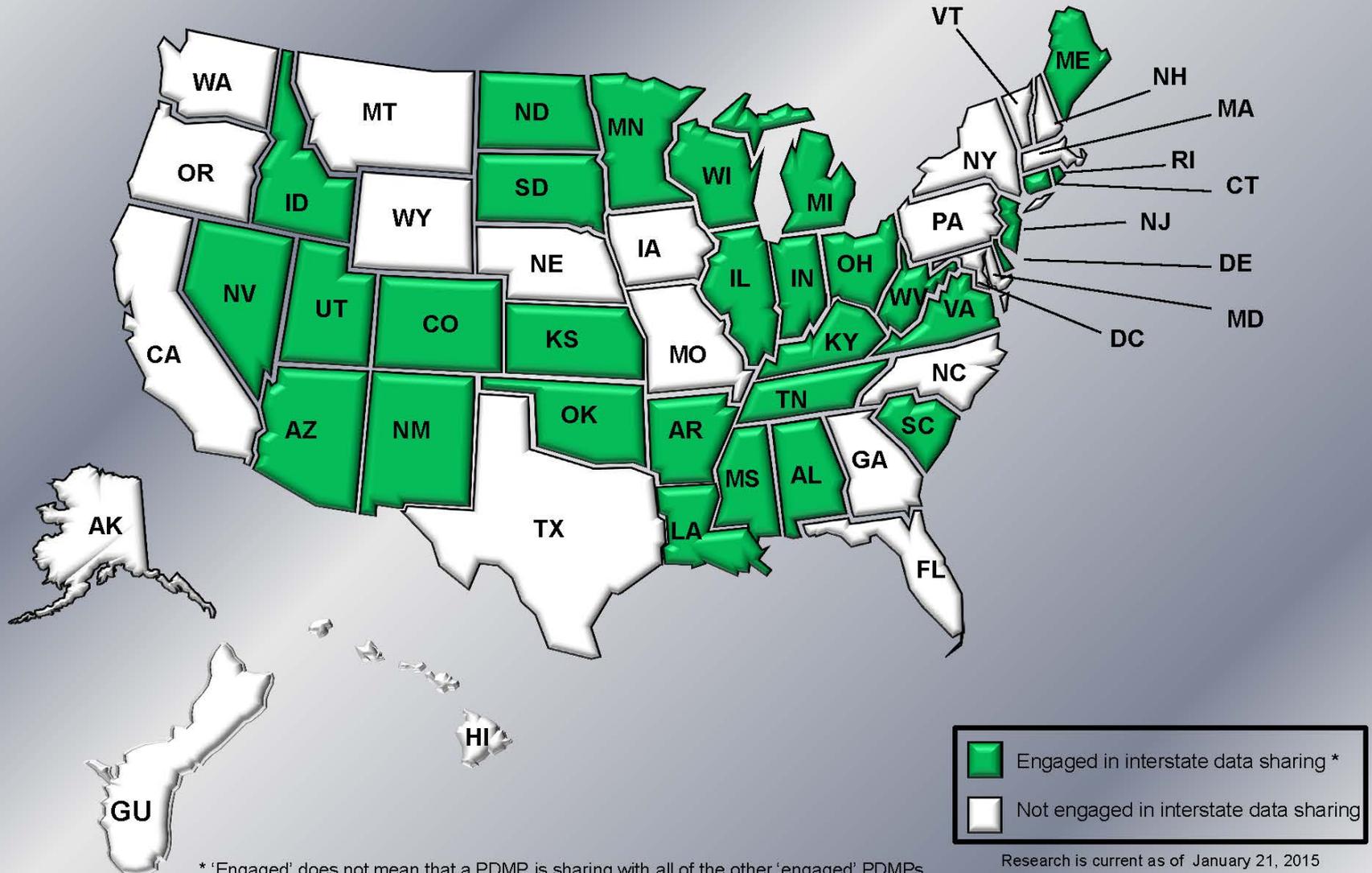
- PDMP in every state and interoperability among states.
- Use of the system by prescribers to identify patients potentially at risk for or engaged in prescription drug misuse or at risk for medication interaction.

Main Actions

- Urged adoption of language for Department of Veterans Affairs to share prescription drug data with state PDMPs.
- Expansion of state data sharing across state lines.
- Electronic Health System Integration: Pilot projects with ONC and SAMHSA in Illinois, Indiana, Kansas, Michigan, Nebraska, North Dakota, Ohio, Oklahoma, Tennessee, and Washington State.

PDMP Training & Technical Assistance Center

Prescription Drug Monitoring Programs (PDMPs) Interstate Data Sharing Status



'High Utilizers' Decreased When Prescribers Required to Consult PDMPs

- Tennessee's PDMP law went into effect at the start of 2013.
- Prescribers now must access the PDMP before prescribing opioids to a new patient.
- "High utilizer" defined as a person who used 5 prescribers and 5 pharmacies in a 90-day period.
- High utilizers decreased 47 percent from the fourth quarter of 2011 to the fourth quarter of 2013.

Source: Tennessee Department of Health Controlled Substance Monitoring Database Committee. Controlled Substance Monitoring Database 2014 Report to the 108th Tennessee General Assembly, February 1, 2014. Page 5. Available at

http://health.tn.gov/statistics/Legislative_Reports_PDF/CSMD_AnnualReport_2014.pdf Linked to 9-04-2014
10/6/2014

Making a Difference: State Successes



2012 Action:

New York required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a **75% drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.



2010 Action:

Florida regulated pain clinics and stopped health care providers from dispensing prescription painkillers from their offices.

2012 Result:

Saw more than **50% decrease in overdose deaths** from oxycodone.



2012 Action:

Tennessee required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a **36% drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

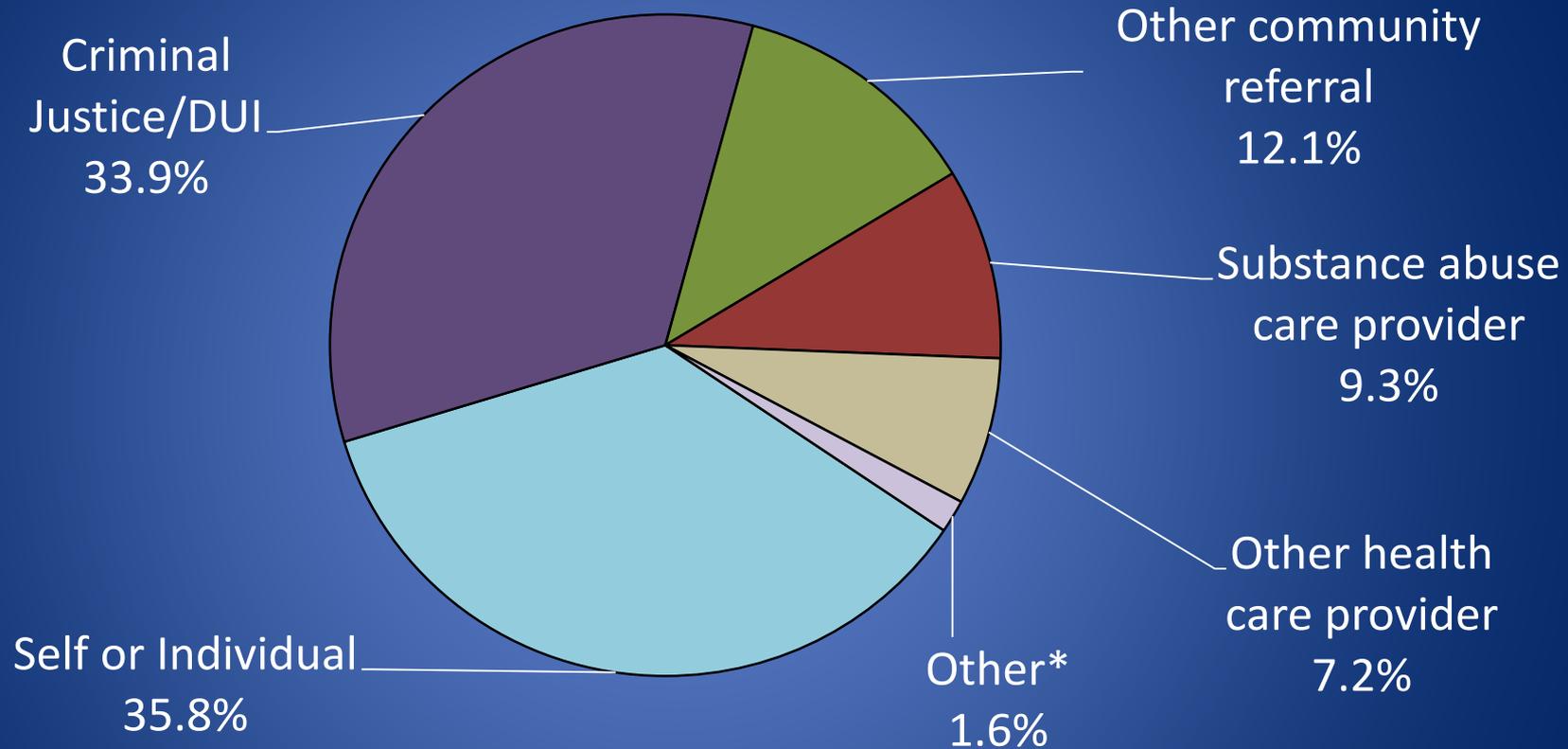
Promising Practice: Pharmacy or Provider Restriction Programs

- Programs which can limit patients based on unusual claims data to a single provider, pharmacy, or both.
- In Medicaid, lock-in period cannot be indefinite, and patients must:
 - “Have access to Medicaid programs of adequate quality.”
 - Be notified in writing.
- Only 46 states have these programs, and 16 post their eligibility criteria publicly.
- **More research is needed on effectiveness for reducing overdose or the prevalence of substance use disorders.**

Safe Drug Disposal

- In September 2014, we joined the Drug Enforcement Administration to announce the final rule of the Safe Drug Disposal Act of 2010.
 - http://www.dea.gov/diversion.usdoj.gov/drug_disposal/take_back/
- Product Stewardship Model: King County, WA, and Alameda County, CA
 - <http://kingcountysecuremedicinereturn.org/>
 - <http://www.acgov.org/aceh/safedisposal/>

Sources of Referral to Treatment, 2012



Total 2012 admissions = 1.7 million

**Other referrals include school (educational) and employer EAP.*

Source: SAMHSA, 2012 Treatment Episode Data Set (July 2014).

Expanding Access to Evidence-Based Treatment

- FY16 Budget includes \$11.0 billion in funding for treatment.
- Inventory treatment availability and work within Affordable Care Act/state-run health marketplaces to ensure proper resourcing.
- Included language in DOJ and HHS drug court grants to expand access to medication-assisted treatment.

Medication-Assisted Treatment

EXPANDING ACCESS

Medication and Treatment

- Medication does not exist to treat all drug use disorders, but it can be effective for opioid use disorder and polypharmacy when combined with behavioral treatment.
- **Medication-Assisted Treatment (MAT) is the standard of care for opioid use disorder**
- MAT is more effective than no MAT for opioid use disorder
 - 50% abstinent at the end of active treatment vs 8% when medication is withdrawn (e.g., detox)

Medications Currently Available

For Nicotine Use Disorder

- Nicotine Replacement Therapies (NRT)
- Bupropion
- Varenicline

For Alcohol Use Disorder

- Disulfiram
- Naltrexone
- Acamprosate
- Naltrexone Depot

For Opioid Use Disorder

- Methadone
- Naltrexone (Vivitrol)
- Buprenorphine
- Buprenorphine/Naloxone



Medical Innovations in the Pipeline

- Buprenorphine HCl Implant^{1,3}
 - Under review at FDA
 - Long-acting (up to 6 months)
 - Implanted under the skin as an office procedure
 - According to FDA guidance, implants are a type of abuse-deterrent medicine and theoretically decrease risk of misuse because patients cannot easily remove them³
- Anti-Opioid Vaccines⁴

Preventing Heroin, Injection-Drug Use, and Medical Consequences

- Non-Medical Use of Prescription Drugs and Prescription Drug Diversion (Rx Plan Pillars)
- Overdose Education and Naloxone Distribution
- Earlier Treatment as Prevention
- Public Health Prevention Interventions for HIV/HEP C
- Medication-Assisted Treatment (Maintenance)

HIV/Hepatitis C Risk Reduction: Substance Use Disorder Treatment as Prevention

- The CDC reported that new hepatitis C infections increased 44.7 percent between 2007 and 2011.¹
- From 2006 to 2012, surveillance data from Kentucky, Tennessee, Virginia, and West Virginia showed an increase (364%) in the number of cases of acute HCV infection among young persons (age 30 or younger); many of these young people reported injection drug use.²
- As of August 28, 2015, Indiana Department of Health diagnosed HIV infection in 181 persons in a community of 4,200 (80 percent reported injection drug use).³

1. <http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/PDFs/2011HepSurveillanceRpt.pdf>

2. Zibbell et al. Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged ≥30 Years – Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012. *MMWR* 2015; 64(17); 453-458.

3. Indiana State Department of Health press release

https://secure.in.gov/isdh/files/August_28_ISDH__Investigates_Additional_HIV_Cases_Tied_To_Southeastern_Indiana_Outbreak.pdf

Pre-Exposure Prophylaxis for HIV

- Pre-exposure Prophylaxis (PrEP) is a daily oral medication to prevent HIV infection.
- US Public Health Service Guideline recommends PrEP as an HIV prevention option for people who inject drugs who:
 - Are HIV negative;
 - Have injected in the past 6 months and
 - Shared injection equipment, or
 - Have been in drug treatment, or
 - Are at risk for sexual acquisition of HIV.

US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. Available at <http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>.

Overdose Prevention and Education

The *National Drug Control Strategy* supports comprehensive overdose prevention efforts, to include:

- Public education campaigns
- Naloxone expansion
- Increased education

ONDCP & Federal Partners Are Working To Expand Access to Naloxone

- HHS is working to support development and approval of alternative routes of administration
 - Autoinjector and Nasal Naloxone Formulas approved since 2014
- Engagement with insurers and pharmacy benefits managers to raise awareness of naloxone
- Naloxone Toolkits for stakeholders – DOJ and SAMHSA
- Co-prescribing – VA included naloxone on formulary for VA mail-order pharmacy and policies
- DOJ encouraging naloxone adoption by Federal law enforcement
- HRSA grants to rural communities
- SAMHSA Block Grant to support training/education and purchase of naloxone

FY 2016 Budget

CDC:

- \$68.0 million (Rx Overdose)
- \$5.6 million (Heroin)

SAMHSA:

- \$25.1 million (MAT)
- \$12 million (Naloxone)
- \$10 million (SPF-Rx)

ONC:

- \$5.0 million for PDMP integration with EHRs

ONDCP:

- \$85.7 million (DFC)
- \$193.4 million (HIDTA)

President Barack Obama at the West Virginia Community Forum

"It touches everybody – from celebrities to college students, to soccer moms, to inner city kids. White, black, Hispanic, young, old, rich, poor, urban, suburban, men and women. It can happen to a coal miner; it can happen to a construction worker; a cop who is taking a painkiller for a work-related injury. It could happen to the doctor who writes him the prescription."



Presidential Memorandum—Addressing Prescription Drug Abuse and Heroin Use

Purpose:

- Reduce prescription pain medication and heroin overdose deaths;
- Promote the appropriate and effective prescribing of pain medications; and
- Improve access to treatment.

Source: MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES
Addressing Prescription Drug Abuse and Heroin Use. The White House Office of the Press Secretary. Available at <https://www.whitehouse.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin>
Linked to October 29, 2015

Research Questions

- Ideal makeup of the pain/healthcare workforce?
- What training is necessary/sufficient?
- Cost-effectiveness of training
- How can we engineer pharmacy utilization controls, decision support tools, and policies to make meaningful change?
- How much Medication Assisted Treatment Is Enough?
- How can we be sure overdose patients who need access to services and treatment move to long-term recovery

Additional 2015 White House Announcements

- Federal Actions
- FY2016 Budget
- State/Local/Private Sector Commitments

Source: FACT SHEET. Obama Administration Announces Public and Private Sector Efforts to Address Prescription Drug Abuse and Heroin use. White House Office of the Press Secretary. October 21, 2015. Available at <https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector>
Linked to October 29, 2015.

Prevention Resources

getsmartaboutdrugs.gov

teens.drugabuse.gov

familycheckupguide.gov

whitehouse.gov/ondcp

ATIpartnerships.org

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 - [WhiteHouse.gov/ONDCP](https://www.whitehouse.gov/ONDCP)
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