Making Health Care Better

Addressing Substance Use Disorders:

Progress in Prevention, Treatment, Recovery and Research

Health Care in America: Making Progress for People with Substance Use Disorder

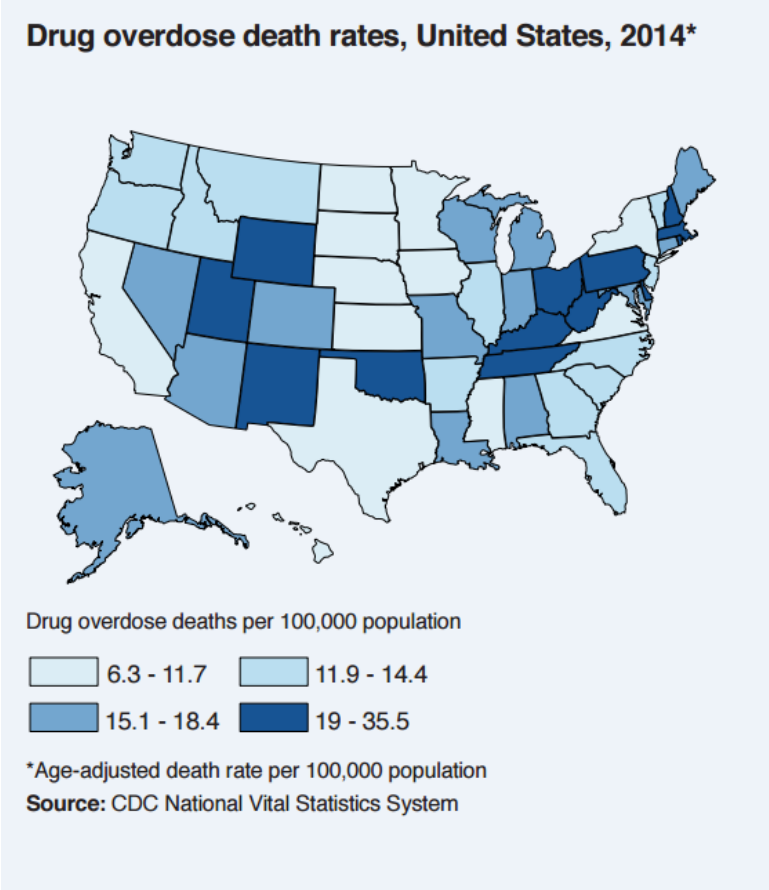
President Obama made health care reform a reality for America. He also recognized that substance use disorders, commonly referred to as addictions, are a health and public health issue. The reforms stemming from the Affordable Care Act (ACA) and other efforts in health care and public health, are greatly improving health care across the nation, enabling Americans to get healthy and stay healthy. Thanks to the ACA, 20 million American adults have gained health insurance coverage.

These changes have made a meaningful impact on the lives of people across the nation. Americans generally can no longer be denied coverage because of pre-existing conditions, including substance use disorders; women cannot be charged more solely on their gender; many Americans with health coverage have access to recommended preventive screenings and services, such as alcohol misuse screening and counseling, depression screening, and tobacco use screening and cessation interventions without cost sharing; and there are generally no more lifetime or annual dollar caps on certain types of care patients receive.

This document highlights how policy actions taken over the past eight years have expanded resources and protections for people with substance use disorders. While people with substance use disorders may also have co-occurring mental health disorders and there is overlap in the systems and programs that serve them, this document is focused on substance use disorders. Earlier, the White House released a summary of the Administration's work to marshal efforts across government and partner with communities to ensure people get the mental health care they need.

The Impact of Substance Use Disorders

Millions of American households are affected by substance use disorders. Substance use disorders occur when the recurrent use of alcohol and/or drugs causes clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home. In 2015, about 20.8 million Americans ages 12 and older were classified with a substance use disorder related to their use of alcohol or illicit drugs in the past year, including 15.7 million people who had an alcohol use disorder and 7.7 million people who had an illicit drug use disorder.[1] Left untreated, substance use disorders can have serious effects on individuals' lives. Substance use disorders can disrupt families and careers and even lead to death; deaths from drug overdose, which also can happen from drug misuse without a disorder, have risen steadily over the past two decades and have become the leading cause of injury death in the United States.[2] People with substance use disorders are more likely to experience economic hardship, emotional distress, legal problems, and interpersonal violence.[3] Children who have a family member with a substance use disorder have a higher risk of developing a substance use disorder later in life.[4]



People with severe mental illness such as schizophrenia or bipolar disorder have a higher risk for substance use. Studies estimate that people diagnosed with mood or anxiety disorders are about twice as likely as the general population to also suffer from a substance use disorder.[5] In 2013, 2.3 million adults had a co-occurring substance use disorder and serious mental illness.[6] Mental disorders also complicate the care of chronic health conditions. For example, co-occurring psychiatric conditions and chronic medical conditions are associated with significantly more expensive care due in large part to poor self-care and more acute episodes of needed health care.[7]

What Has Changed for People with Substance Use Disorders

President Obama recognized the importance of making real, lasting changes to ensure that people with substance use disorders receive the services and supports they need. Since President Obama took office, there have been several key changes in access to and delivery of quality health services in the health system that also benefit people with substance use disorders, including:

- New opportunities for coverage and quality of care under the ACA include:
    - Expanded private insurance and Medicaid coverage, enabling people with substance use disorders to have access to quality, affordable health coverage.
    - Delivery system reforms, including improvements to how hospitals, doctors, and other providers operate to deliver better care at lower cost.
    - New Medicaid initiatives to integrate mental health and substance use disorder care with primary health care.
    - Improvements to the Medicare Part D program that make prescription drugs, including buprenorphine treatment for opioid use disorder, more affordable by reducing cost sharing.
    - Coverage of certain recommended standardized benefits for the non-grandfathered individual and small group markets by requiring coverage of the essential health benefits that included requiring coverage of mental health and substance use disorder services.
- Improved approaches to quality mental health and substance use disorder care, including prevention and early detection.
- Regulations putting mental health and substance use disorder benefits on equal footing with medical and surgical benefits – also known as mental health and substance use parity – in all types of private insurance, under the Medicaid and Children's Health Insurance Program (CHIP) programs, and the military's TRICARE program.
- Helping States and communities improve mental health and substance use disorder health care and put strong infrastructure in place to improve access to care, including increasing the number of providers who treat mental health and substance use disorders.
- Making major strides and developments in biomedical research to help diagnose and treat mental health and substance use disorders.
- Allowing States to supplement co-pays and deductibles for substance use disorder treatment using the Substance Abuse Prevention and Treatment Block Grant

- New regulations to allow more health care providers to provide medication assisted treatment (buprenorphine) to additional patients.

The Affordable Care Act and Substance Use Disorders

Access to quality, affordable health care is essential in the effort to improve care of substance use disorders in the U.S. Those affected by substance use disorders should not have to choose between health care and other basic needs. That is why this Administration fought so hard for the ACA, which has helped 20 million uninsured Americans gain the security they deserve. Under the ACA:

- As many as 129 million Americans with pre-existing conditions, including substance use disorders, can no longer be denied coverage or charged more because of their health or family health history.
- Lifetime or annual dollar caps on coverage of essential health benefits, which could disrupt substance use disorder treatments, are prohibited for most plans.
- Out-of-pocket costs for consumers enrolled in non-grandfathered group health plans and individual coverage are limited, helping them to maintain financial stability, even in the face of illnesses like substance use disorder.
- Americans enrolled in non-grandfathered coverage have the right to appeal decisions made by their health plan to external review.
- Most health insurance plans are required to provide in-network coverage for certain recommended preventive services without cost sharing. This includes services such as alcohol misuse screening and counseling, depression screening, and tobacco use screening and cessation interventions.

More Americans with insurance means more people are receiving services to screen for, manage, and treat substance use disorders. The ACA created the largest expansions of mental health and substance use disorder coverage in a generation by requiring that most individual and small employer health insurance plans, including all plans offered through the Health Insurance Marketplace, cover essential health benefits including mental health and substance use disorder services. The ACA also expanded parity protections to this coverage, as well as covering rehabilitative and habilitative services that can help support people with mental health and substance use disorder.[8]

Prior to the ACA, 47.5 million Americans lacked health insurance, and 25 percent of uninsured adults had a mental health condition, substance use disorder, or both.[9] Estimates indicate that the ACA expanded mental health and substance use disorder benefits and parity protections to

more than 60 million people.[10] Treatment for substance use disorder can no longer be excluded from coverage as a pre-existing condition.

Furthermore, the ACA increased mental health service utilization among young adults that obtained insurance coverage due to the ACA's requirement that young adults be able to remain on parent's plan until age 26, as expanded insurance coverage removes significant cost barriers to seeking treatment.[11] The young adult policy has resulted in increased use of private insurance for mental health and substance use disorder treatment, and it has lowered the likelihood by 54 percent of young adults with one of these health conditions having to pay 75 percent or more of their medical expenses out of pocket.[12] [13]

The ACA enhanced coverage of preventive services. Most private health plans must now cover preventive services, such as alcohol misuse screening and counseling, depression screening, and tobacco use screening for all adults and cessation interventions for tobacco users, without charging a copayment, coinsurance, or deductible. This also includes Women's Preventive Services guidelines that have provided more than 55 million women with guaranteed access to eight additional preventive services, including screening and counseling for interpersonal and domestic violence.[14] In addition, States were offered incentives to offer preventive services to Medicaid beneficiaries. Today, about 137 million Americans have private insurance coverage of preventive services without cost sharing.[15] Preventing mental and/or substance use disorders is critical to Americans' overall health.

Medicaid expansion is a significant benefit for individuals with substance use disorders. In the States that have expanded their Medicaid programs under the ACA, there has been a reduction in the unmet need for mental health and substance use disorder treatment among low-income adults.[16] People with mental and/or substance use disorder health needs make up nearly 30 percent of all low-income uninsured individuals in States that have not yet expanded Medicaid. Low-income adults with serious mental illness and substance use disorders are significantly more likely to receive treatment if they have access to Medicaid coverage. In 2014, the most recent year for which data are available, an estimated 1.9 million uninsured people with a mental illness or substance use disorder lived in States that have not yet expanded Medicaid under the Affordable Care Act and had incomes that could qualify them for coverage. States that choose to expand Medicaid may achieve significant improvement in their mental/substance use disorder health programs without incurring new costs. Therefore, State funds that currently support mental/substance use treatment for people who are uninsured but would gain coverage under expansion could become available for other mental/substance use investments.[17]

Parity in Insurance Coverage

The Obama Administration has taken action to implement the Mental Health Parity and Addiction Equity Act (MHPAEA), a major step forward in putting mental health and substance use disorder health care on equal footing with medical and surgical care. MHPAEA requires comparability in any restrictions imposed on medical/surgical and mental health and substance use disorder health coverage. In addition, the ACA extended parity protections to individual health plans, and regulations implementing the ACA's essential health benefits requirements extended parity protection to the small group market coverage.[18]

Separate legislation extended parity protections to Medicaid managed care plans, CHIP, and Alternative Benefit Plans (ABPs). The Administration recently implemented those provisions in a final rule adopted in 2016.

To further expand these efforts, earlier this year, the Department of Defense (DOD) issued a final rule to apply the principles of mental health and substance use disorder parity to TRICARE, the health benefits program from uniformed service members and their families. As of September 2016, TRICARE had an estimated 15,000 to 20,000 beneficiaries with opioid use disorder who previously could not access medication-assisted treatment (MAT) who now have the opportunity to benefit from this rule.

Overall employer-sponsored large group plans have made meaningful improvements to their mental health and substance use disorder benefits. For example, the vast majority of these plans have eliminated higher cost sharing for inpatient and outpatient mental health and substance use disorder health care. There have also been significant declines in the use of limits to the number of days or visits covered for mental health and substance use disorder health care. This has resulted in expanded access to care for adults and children with these conditions.[19,20,21,22,23,24] At the same time, the Administration is working to ensure parity compliance among non-quantitative treatment limits like pre-authorization requirements. States are becoming involved as well. A major insurer recently announced it would eliminate pre-authorization nationwide for buprenorphine as part of a settlement of a parity investigation brought by the New York Attorney General.

To ensure that health plans are appropriately complying with parity and that consumers and health care providers understand parity protections, the President recently established the Mental Health and Substance Use Disorder Parity Task Force to promote compliance with parity best practices, support the development of tools and resources to support parity implementation, and develop additional agency guidance as needed to facilitate the implementation of parity.

The Mental Health and Substance Use Disorder Parity Task Force was led by the White House Domestic Policy Council and consisted of the Departments of Labor, the Treasury, Defense, Justice, Health and Human Services, and Veterans Affairs, as well as the Office of Personnel Management and the Office of National Drug Control Policy. Between March and October of 2016, the Task Force met with various stakeholders including consumers, providers, employers, health plans, and State regulators, and received more than 1,100 public comments.

In October 2016, the Mental Health and Substance Use Disorder Parity Task Force presented President Obama its final report, which included both action steps and recommendations to ensure that any limitations on coverage for mental health and substance use disorder services are comparable to – or at parity with – any such limitations on coverage for general medical care. New actions announced as part of the report included:

- The Centers for Medicare & Medicaid Services (CMS) awarded $9.3 million to States to help enforce parity protections. CMS funding will help State insurance regulators work to ensure issuer compliance with the mental health and substance use disorder parity protections.
- The Department of Health and Human Services (HHS), in partnership with the Department of Labor (DOL) and other Task Force agencies, released the beta version of a new parity website to help consumers find the appropriate Federal or State agency to assist with their parity complaints, appeals, and other actions. The Task Force received many comments about the challenges consumers face in identifying the appropriate agency that regulates their insurance coverage. The beta site was released for public comment. In the future, the Task Force Departments intend to work together to enhance the functionality of the website with the addition of complaint and data tracking.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) and DOL released a *Consumer Guide to Disclosure Rights: Making the Most of Your Mental Health and Substance Use Disorder Benefits* to help consumers, their representatives, and providers understand what type of information to ask for when inquiring about a plan's compliance with parity and to explain the various Federal disclosure laws that also require disclosure of information related to parity. The Guide includes 11 scenarios, each with specific suggestions for information consumers have a right to that can help, as well as timing requirements for plans and issuers providing these documents.
- DOL announced that it will release annual data on closed Federal parity investigations and will report on the findings, including the violations cited to ensure parity compliance and inform future policymaking efforts. This effort builds on the 1,515 investigations related to MHPEA and 171 violations cited by DOL since October of 2010.
- To ensure parity compliance in plans required to offer essential health benefits, CMS reviews plans subject to the essential health benefits requirement under the Affordable

Care Act for compliance with MHPEA parity requirements, and it expects State regulators to do so as well.

- The Office of Personnel Management released a 2017 Call Letter to health plans participating in the Federal Employees Health Benefits Program (FEHBP) making opioid use disorder treatment a priority and calling on health plans to review and improve access to medication-assisted treatment.
- DOL, HHS, and the Department of Treasury (Treasury) issued guidance on parity and opioid use disorder treatment to address specific questions the Departments have received related to issues such as the application of parity to opioid treatment access and coverage of court-ordered treatment.
- HHS, DOL, and Treasury are soliciting feedback on how the disclosure document request process can be improved, while continuing to ensure consumers' rights to access all appropriate information and documentation. The request solicits input on the option of developing model forms for parity-related disclosure requests.
- SAMHSA announced that it will host two State Policy Academies on Parity Implementation for State Officials in Fiscal Year 2017, including one focused on the commercial market and one on parity in Medicaid and the Children's Health Insurance Program. These policy academies will bring together national experts to provide technical assistance to teams of State officials on strategies to advance parity compliance and lessons learned from other States' implementation efforts.
- CMS will undertake a review of mental health and substance use disorder benefits in Medicare Advantage plans and identify any necessary improvements to advance parity protections.
- DOL, HHS, and Treasury issued a Parity Compliance Assistance Materials Index. The Departments have issued a total of 44 Frequently Asked Questions (FAQs) over the past six years related to parity, generally as part of larger guidance documents, as well as other parity materials. Several commenters suggested to the Task Force that putting all the parity-related FAQs and guidance together in one place would make the information easier to find and use for States, plans, consumers, and other stakeholders.

The Task Force also made the following recommendations:

- Create a one-stop consumer web portal to help consumers navigate parity, which will build out the functionality of the beta parity website.
- Increase Federal agencies' capacity to audit health plans for parity compliance.
- Undertake a detailed review of the non-quantitative treatment limits applicable to substance use disorder benefits in the Federal Employees Health Benefits (FEHB) Program.
- Allow DOL to assess civil monetary penalties for parity violations.

- Develop examples of parity compliance best practices and of potential warning signs of non-compliance.
- Provide Federal support for State efforts to enforce parity through trainings, resources, and new implementation tools, including model compliance templates. Further, the Task Force recommended that Federal regulators work with the National Association of Insurance Commissioners and the States to develop a standardized template that States might use to help assess parity compliance. The Task Force also encouraged Federal regulators, the National Association of Insurance Commissioners, and other stakeholders to consider a joint effort to develop a model prior authorization form and other model forms.
- Provide simplified disclosure tools to provide consistent information for consumers, plans and issuers. To facilitate disclosure, the Task Force recommended that, in coordination with the National Association of Insurance Commissioners, templates and other sample standardized tools be developed to improve consumer access to plan information.
- Expand consumer education about parity protections. The Task Force recommended continuing and expanding the work to educate consumers about parity and partnering with consumer groups to increase consumer awareness and understanding of parity protections.
- Clarify that health plan disclosure requirements include medical and surgical benefits. Disclosure of the relevant information used to apply coverage limitations to medical and surgical services is currently required for plans covered under the Employee Retirement Income Security Act (ERISA). The Task Force recommended that Congress extend this requirement to non-ERISA plans.
- Implement the Medicaid and CHIP parity final rule in a robust manner. The Task Force recommended that implementation include the development of a parity analysis toolkit to help States assess compliance with the final rules on parity for Medicaid managed care organizations and CHIP programs.
- Expand access to mental health and substance use disorder services in TRICARE. The Task Force recommended DOD continued implementation of the TRICARE final rule on mental health and substance use disorders and parity through contract modifications and DOD's monitoring of access to mental health and substance use disorder care to ensure parity with medical/surgical care.
- Eliminate the lifetime day limit on Medicare Part A treatment in psychiatric hospitals.
- Update guidance to address the applicability of parity to opioid use disorder services.
- Eliminate the parity opt-out process for self-funded non-Federal governmental plans.

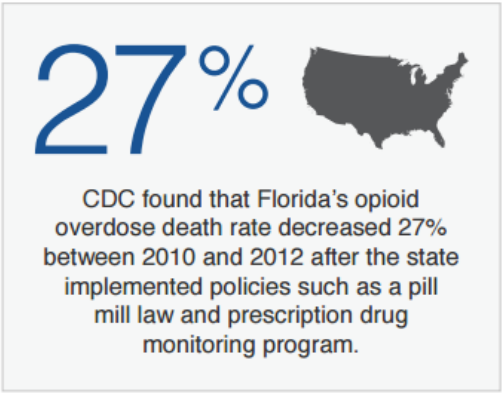
Advancing a Public Health and Public Safety Approach

This Administration continues to invest in prevention, early detection, treatment and recovery as public health priorities. These actions build on efforts that began in 2010 when President Obama released his first National Drug Control Strategy, which emphasized the need for action to address opioid use disorders and overdose while ensuring that individuals with pain receive safe, effective treatment. In 2011, the White House released its national Prescription Drug Abuse Prevention Plan, which outlined goals for addressing prescription drug misuse and overdose. Since then, the Administration has supported and expanded efforts to prevent drug use, pursue "smart on crime" approaches to drug enforcement and disrupt drug trafficking networks, improve prescribing practices for pain medication, increase access to treatment, work to reduce overdose deaths, and support the millions of Americans in recovery:

- President Obama's FY 2017 Budget called for $1.1 billion in new funding to address the prescription opioid and heroin overdose crisis. This funding includes:
  - $920 million to support cooperative agreements with States to expand access to medication-assisted treatment for opioid use disorders. States will receive funds based on the severity of the epidemic and on the strength of their strategy to respond to it. States can use these funds to expand treatment capacity and make services more affordable.
  - $70 million in National Health Service Corps funding to support an additional 1,200 providers to expand access to substance use treatment providers. This includes: (1) $25 million as part of a new initiative to expand access to treatment to reduce prescription drug misuse and heroin use, with a focus on expanded use of MAT; (2) $25 million as part of the Administration's initiative to expand access to mental health care; and (3) $20 million to address the demand in high-need areas for health providers to treat substance use disorders.
  - $30 million to evaluate the effectiveness of treatment programs employing medication-assisted treatment under real-world conditions and help identify opportunities to improve treatment for patients with opioid use disorders.
- The President's FY 2017 budget proposals would continue and build on current efforts across the Departments of Justice (DOJ) and HHS to expand State-level prescription drug overdose prevention strategies, increase the availability of MAT programs, improve access to the overdose-reversal drug naloxone, and support targeted enforcement activities. A portion of this funding is directed specifically to rural areas, where rates of overdose and opioid use are particularly high.
- ONDCP, in collaboration with SAMHSA, supports local Drug-Free Communities coalitions to reduce youth substance misuse through evidence-based prevention. In recent years,

hundreds of these coalitions have specifically focused on prescription drug misuse issues in their areas.

- The ACA both expanded private insurance coverage for preventive services including mental health/substance use screenings and invested in community-based prevention initiatives through the Prevention and Public Health Fund which provides sustained national investments in prevention and public health to improve health outcomes and to enhance health care quality.[25]
- The Administration has also doubled the size of the National Health Service Corps whose providers help reach communities that need them most and minimize patients' travel distances to seek care. Today, almost 3,000 mental and behavioral health clinicians serve in the Corps and practice in designated health care shortage areas.
- SAMHSA and the Health Resources and Services Administration (HRSA) collaborated to increase the supply of mental health professionals and paraprofessionals across the country as part of the White House's *Now is the Time* initiative. From FY 2014 - FY 2016, this program received a total of $120 million in funding to increase the number of behavioral health providers serving children, adolescents, and transitional-age youth who have, or are at risk of, developing behavioral health disorders.
- HRSA's Graduate Psychology Education Program helps prepare psychologists to provide behavioral health care, including substance abuse prevention and treatment services, in a setting that provides integrated primary and behavioral health services to underserved and/or rural populations. The Program supports hundreds of students and fellows each year in their clinical training to support these vulnerable communities.
- To continue the important conversations happening in rural communities devastated by the opioid epidemic, leaders from the US Department of Agriculture's (USDA) Farm Service Agency and Rural Development offices in key affected States have begun hosting opioid epidemic awareness forums to bring together government officials, medical professionals, law enforcement, and other stakeholders to raise awareness of the issue, forge partnerships, identify possible solutions, and highlight the need for more treatment resources in rural communities. The series kicked off with four forums in September 2016.
- The Drug Enforcement Administration (DEA) and HHS have released prevention public service announcements (PSAs) for TV and radio. One set of PSAs was filmed in Scott County, Indiana—which experienced an HIV outbreak last year linked to injection opioid misuse.
- The DOJ COPS program announced a $7 million funding opportunity called the COPS Anti-



Heroin Task Force Program to advance public safety and to investigate the distribution of heroin, unlawful distribution of prescription opioids and unlawful heroin and prescription opioid traffickers. These grants provide funds directly to law enforcement agencies in States with high rates of primary treatment admissions for heroin and other opioids.

- As part of Prescription Opioid and Heroin Epidemic Awareness Week in 2016, DOJ issued a memorandum to Federal prosecutors to reinforce the Administration's prevention, enforcement, and treatment strategy and institutionalize best practices in combatting the epidemic. The memorandum built on the work DOJ has been undertaking around the country to address the issue. DOJ also announced funding to strengthen Prescription Drug Monitoring Programs (PDMPs) across the country and grants to support State-level law enforcement investigations of drug manufacturing and drug distribution networks.
- The Education Secretary has also sent letters to educators across the country on the important role that schools can play in preventing youth substance use and in supporting students who need treatment or are in recovery.
- To reduce the risk of alcohol-related harms, the National Institute on Alcohol Abuse and Alcoholism developed and promoted evidence-based resources to assist health care and other professionals in detecting, preventing, and intervening with alcohol misuse, especially among adolescents and young adults.[26]

The Federal government has taken action to strengthen law enforcement to reduce the supply of illicit substances in communities nationwide:

- ONDCP's High Intensity Drug Trafficking Areas program is funding an unprecedented network of public health and law enforcement partnerships to address the heroin threat across 20 States.
- DEA has deployed a 360 Strategy targeting the opioid epidemic through coordinated law enforcement operations, diversion control and partnerships with community organizations following enforcement operations.
- DOJ's enforcement efforts include targeting the illegal opioid supply chain, thwarting doctor-shopping attempts, and disrupting so-called "pill mills."
- DOJ has cracked down on those who use the Internet to illegally buy and sell controlled substances.
- As of September 2016, DEA has trained 1,033 employees in DEA Field Divisions on how to administer the overdose-reversal medicine naloxone. In early 2016, DEA's Training Division coordinated two Train-the-Trainer programs for 65 DEA Emergency Medical Technicians (EMTs). These 65 EMTs were then certified to conduct a four-hour class on naloxone, CPR, and Automated External Defibrillator (AED) use for employees.
- Since 2007, through the Merida Initiative, the Department of State has been working with the Government of Mexico to help build the capacity of Mexico's law enforcement and

justice sector institutions to disrupt drug trafficking organizations and to stop the flow of illicit drugs including heroin from Mexico to the United States.

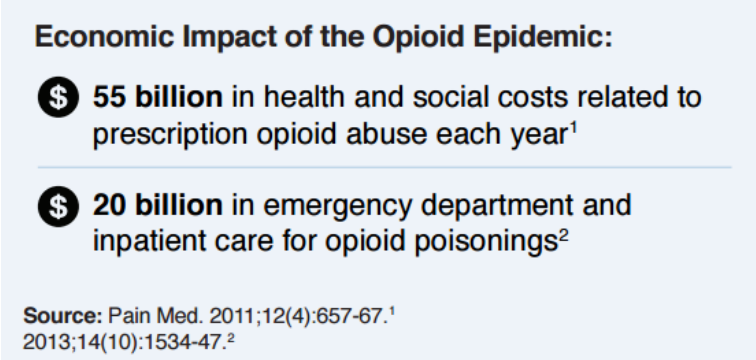
- DEA issued a final rule in October 2014 that reclassified hydrocodone combination products to a more restrictive category of controlled substances, along with other opioid prescriptions for pain like morphine and oxycodone. After a scientific review, FDA made the recommendation that DEA take this step in December 2013. Hydrocodone was the most prescribed opioid in the United States, including 137 million prescriptions in 2013. While it is useful in the treatment of pain, it has also contributed significantly to the very serious problem of opioid misuse and opioid use disorder in the United States.[27]
- In September 2016, the Obama Administration announced enhanced measures in conjunction with the Chinese government to combat the supply of fentanyl and its analogues to the United States. China committed to targeting U.S.-bound exports of substances controlled in the United States, but not in China. Additionally, the U.S. and China agreed to increase the exchange of law enforcement and scientific information with a view towards coordinated actions to control substances and chemicals of concern. China is the primary source of precursor chemicals used to manufacture methamphetamine consumed in the United States and the majority of fentanyl and its analogues brought to the United States by drug traffickers originates in China.[28]

Improving Care

The prevention and treatment of substance use disorder can be complex, and its success is often dependent on the provision of quality, coordinated health care. The ACA includes numerous provisions designed to support healthy people and improve the overall health system.

The law promotes the adoption of new care models that improve care coordination, advance measurement of quality and star-rating systems that help patients choose high-performing providers, and that modify how care is paid for to promote the delivery of high-quality, efficient, and affordable mental health and substance use health care.

Substance use and misuse costs our Nation over $400 billion annually and treatment can help reduce these costs.[29] Substance use disorder treatment has been shown to reduce associated health and



- THE TOTAL COST OF PRESCRIPTION OPIOID OVERDOSE, ABUSE, AND DEPENDENCE WAS ESTIMATED TO BE $78.5 BILLION IN 2013.
- OVER ONE THIRD OF THIS AMOUNT ($29 BILLION) WAS DUE TO INCREASED HEALTH CARE AND SUBSTANCE ABUSE TREATMENT COSTS.
- ONE-QUARTER OF THE COSTS WERE PAID FOR BY THE PUBLIC SECTOR IN HEALTH CARE, SUBSTANCE ABUSE TREATMENT, AND CRIMINAL JUSTICE COSTS.

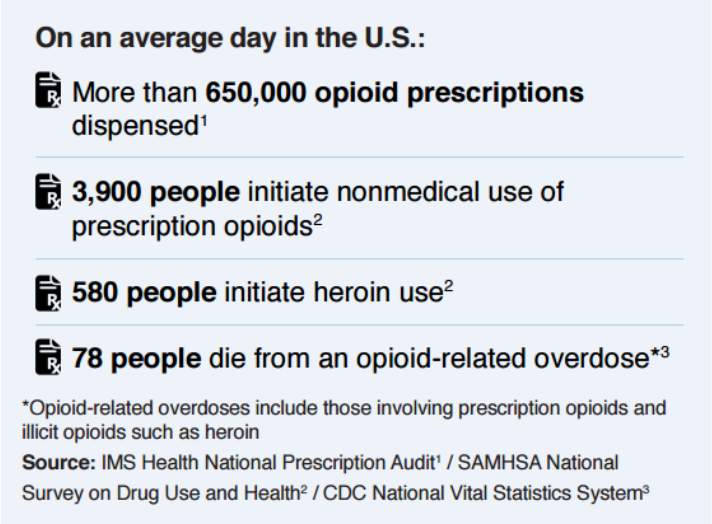
Source: The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care 54: 901-906.

social costs by far more than the cost of the treatment itself.

The Administration has undertaken a number of initiatives to prevent substance use disorder and to improve the access to and quality of care for individuals with substance use disorders:

- In October 2015, President Obama issued a Memorandum to Federal Departments and Agencies directing two important steps to combat the prescription opioid misuse and heroin epidemic:
    - Prescriber Training: First, to help ensure that health care professionals who prescribe opioids are properly trained in opioid prescribing and to establish the Federal Government as a model, the Presidential Memorandum requires Federal Departments and Agencies to provide training on the prescribing of these medications to Federal health care professionals who prescribe controlled substances as part of their Federal responsibilities.
    - Improving Access to Treatment: Second, to improve access to treatment for prescription drug misuse and heroin use, the Presidential Memorandum directs Federal Departments and Agencies that directly provide, contract to provide, reimburse for, or otherwise facilitate access to health benefits, to conduct a review to identify barriers to MAT for opioid use disorders and develop action plans to address these barriers.
- The Centers for Disease Control and Prevention (CDC) issued its Guideline for Prescribing Opioids for Chronic Pain – the Agency's first-ever recommendations for primary care clinicians on prescribing opioids. The Guideline provides recommendations for clinicians on appropriate prescribing, including determining if and when to start prescription opioids for chronic pain treatment; guidance on medication selection, dose, and duration, including when to discontinue medication, if needed; and guidance to help assess the benefits and risks and address the harms of prescription opioid use. The guideline is intended for patients 18 and older in primary care settings. Recommendations focus on

the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. The guideline was released to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these medications.[30]



- In 2016, over 60 medical schools announced that, beginning in fall 2016, they would require their students to take some form of prescriber education, in line with the CDC Prevention Guideline for Prescribing Opioids for Chronic Pain in order to graduate.[31] In addition, nearly 200 nursing schools and more than 50 pharmacy schools committed to prescriber training.
- In August 2016, the Surgeon General sent a letter to 2.3 million health care providers, including doctors, dentists, and nurses, encouraging members of the profession to be leaders in combating the opioid epidemic while treating their patient's pain appropriately.
- In order to mitigate even the perception that there is financial pressure to overprescribe opioids, CMS removed the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain management questions from the hospital payment scoring calculation. This means that hospitals continue to use the questions to survey patients about their in-patient pain management experience, but these questions would not affect the level of payment hospitals receive.[32]
- SAMHSA finalized a rule in July 2016 that allows practitioners who have had a waiver to prescribe buprenorphine for up to 100 patients for a year or more, to now obtain a waiver to treat up to 275 patients. As of October 2016, 2,400 practitioners have applied for and been granted waivers to prescribe at the increased limit—improving access to buprenorphine, which is prescribed along with psychosocial supports as part of MAT. Buprenorphine is one of the drugs frequently used to treat opioid use disorders. [33]
- In November 2016, HHS took steps to expand access to opioid treatment by enabling nurse practitioners (NPs) and physician assistants (PAs) to begin training to prescribe the opioid use disorder treatment, buprenorphine, based on the Comprehensive Addiction and Recovery Act. NPs and PAs who complete the required training will be able to begin

prescribing in February 2017. Previously, only physicians could prescribe buprenorphine. HHS also announced its intent to initiate rulemaking to allow NPs and PAs to prescribe buprenorphine for up to 100 patients.

- While many Indian Health Service (IHS) clinicians already utilize Prescription Drug Monitoring Program (PDMP) databases, IHS now requires its opioid prescribers and pharmacists to check their State PDMP database prior to prescribing or dispensing any opioid for more than seven days. The new policy is effective for more than 1,200 IHS clinicians working in IHS Federally operated facilities who are authorized to prescribe opioids. Checking a PDMP database before prescribing an opioid helps to improve appropriate pain management care, identify patients who may be misusing prescription opioids, and prevent diversion of drugs. This policy builds on IHS efforts to reduce the health consequences associated with opioid use disorder. As a part of this work, IHS has pledged to train hundreds of Bureau of Indian Affairs law enforcement officers on how to use naloxone, and provide them with the life-saving, opioid overdose-reversing drug.[34]
- CMS released a 2017 Call Letter to plans participating in the Medicare Prescription Drug Program reiterating that reducing the unsafe use of opioids is a priority and making clear that Part D formulary and plan benefit designs that hinder access to medication-assisted treatment for opioid use disorder will not be approved.
- CMS released a guidance document to States identifying "Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction" including effective Medicaid pharmacy benefit management strategies, steps to increase the use of naloxone to reverse opioid overdose, and options for expanding Medicaid coverage of and access to opioid use disorder treatment. This builds on Medicaid's work with States to increase access to Medicaid substance use disorder treatment services.
- Nearly 12 percent of adults in Medicaid and 6 percent of adolescents have a substance use disorder. Further, alcohol and drug use diagnoses are two of the top ten reasons for Medicaid hospital readmissions. Many States have found success in implementing policy, program and payment reforms that reduce health care costs and improve the health and health care for Medicaid beneficiaries with substance use disorders.[35]
- CMS has been working through various initiatives to support a number of States to provide more effective care to Medicaid beneficiaries with substance use disorders including opioid use disorder. Through its Medicaid Innovation Accelerator Program (IAP) for Addressing and Reducing Substance Use Disorders, CMS is providing States with strategic and technical support designed to accelerate the development and testing of service delivery innovations for substance use disorder treatments. The types of technical support include assistance with developing bundled payment models for MAT, performing data analytics on the distribution and characteristics of MAT utilization (especially buprenorphine); implementing quality measurement reporting for substance

use disorders; developing resources strategies regarding care transitions and treatment engagement following withdrawal management; designing model substance use disorder opioid health home programs; leveraging strategic and managed care contract language for substance use disorder purchasing; and administrative claims and managed care organization encounter data standardization. In addition, the IAP is connecting States to content experts and leading practices across the country on a number of topics within substance use disorder delivery system reform, such as improving access to MAT, implementing pharmacy benefit management strategies to address opioid use disorder, encouraging participation in Medicaid by providers who treat substance use disorders, and the integration of primary care and SUD services.

- Furthermore, CMS issued guidance on a new opportunity under section 1115 demonstration authority geared to States interested in undertaking treatment delivery system transformation efforts, enabling them to provide a full continuum of care for individuals with substance use disorders, including coverage for short-term residential treatment services not otherwise covered under Medicaid. This section 1115 opportunity supports States' efforts to introduce service, payment and delivery system reforms designed to improve access to and quality of care for individuals with substance use disorders, including access to MAT. CMS has approved two section 1115 demonstrations in California and Massachusetts, and is providing ongoing strategic design support to a number of states to support their 1115 proposals related to substance use disorders.
- In the finalized 2017 Marketplace Payment Notice, CMS affirmed that both essential health benefits requirements and Federal mental health and substance use disorder parity requirements apply to qualified health plan coverage of medications to treat opioid use disorder.
- The finalized regulation that updates payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule in 2017 allows the Medicare program to make separate payments using new codes to pay primary care practices that use interprofessional care management resources to treat patients with mental health and substance use conditions. Several of these codes describe services within behavioral health integration models of care, including the Psychiatric Collaborative Care Model that involves care coordination between a psychiatric consultant or mental health/substance use disorder specialist or manager, and the primary care clinician, which has been shown to improve quality of care.[36]
- Medicare and Medicaid are implementing person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion. This includes the use and distribution of naloxone and increasing access to medication-assisted treatment. The programs are also encouraging the use of evidence-based practices for acute and chronic pain management.

- As part of its efforts to prevent and treat opioid use disorder among Veterans, the Department of Veterans Affairs (VA) released a new policy for its health care providers who prescribe controlled substances that requires them (or where allowed their delegate) in most cases to check State PDMPs prior to deciding to prescribe a new controlled substance to determine if a patient is receiving opioids or other controlled substances from another provider and document that in the electronic patient record. These checks will occur at a minimum once a year and/or when clinically indicated for each renewal or continuation of therapy. VA provides health care services to approximately 8.3 million veterans at 150 medical centers, nearly 1,400 community-based outpatient clinics, community living centers, Vet Centers and Domiciliaries.
- DOD has conducted an evaluation of its prescription drug monitoring program to assess its ability to capture community providers and use of cash transitions; identify any gaps in comprehensive use of prescription drug monitoring strategies; and make recommendations for closing those gaps.
- In September 2016, USDA announced $4.7 in Distance Learning and Telemedicine (DLT) program grants to support 18 projects in 16 States for rural communities to use communications technology to expand access to healthcare, substance use treatment, and advanced educational opportunities. These projects join 80 DLT projects announced in July 2016. DLT grants can be used to connect rural hospitals to larger healthcare facilities through telemedicine in order to better diagnose and treat substance use disorders. In addition to DLT investments, USDA Rural Development has funded rural hospitals and health care clinics from its Community Facilities and Business and Industry Guaranteed Loan Programs. These projects provide communities with much-needed services to help address health care, including overdose and opioid use disorder.
- In 2014, the President signed the Protecting Access to Medicare Act (PAMA), which included a bipartisan demonstration program to expand access to community-based mental health and substance use disorder services for Medicaid beneficiaries with a focus on adults with serious mental illness, children with serious emotional disturbance, and individuals with serious substance use disorders. States have planning grants for this Certified Community Behavioral Health Clinic demonstration, with the demonstration set to launch in 2017 in eight States.
- The ACA created new funding opportunities for Community Health Centers to build, expand, and operate health-care facilities in underserved communities. In March 2016, HHS awarded $94 million to support 271 health centers in 45 States, the District of Columbia, and Puerto Rico to improve and expand the delivery of substance use disorder services in health centers, including MAT, with a specific focus on opioid use disorders. This funding is expected to help health centers treat nearly 124,000 new patients with substance use disorders.[37]

- HHS issued guidance for HHS-funded programs regarding the use of Federal funds to implement or expand syringe services programs for people who inject drugs. Syringe services programs are an effective component of a comprehensive approach to preventing HIV and viral hepatitis among people who inject drugs. The bipartisan budget agreement signed by President Obama in 2015 revised a longstanding ban on these programs and allows communities with a demonstrated need to use Federal funds for the operational components of syringe services programs.
- In November 2016, The Surgeon General's first-ever *Report on Alcohol, Drugs, and Health* addressed alcohol, illicit drugs, and prescription drug misuse, with chapters dedicated to neurobiology, prevention, treatment, recovery, health systems integration and recommendations for the future. It provided an in-depth look at the science of substance use disorders and addiction, called for a cultural shift in the way Americans talk about the issue, and recommended additional actions to prevent and treat these conditions, and promote recovery.

Preventing Overdose Deaths

- As of September 2016, DEA has trained 1,033 employees in DEA Field Divisions on how to administer the overdose-reversal medicine naloxone. In early 2016, DEA's Training Division coordinated two Train-the-Trainer programs for 65 DEA Emergency Medical Technicians (EMTs). These 65 EMTs were then certified to conduct a four-hour class on naloxone, CPR, and Automated External Defibrillator (AED) use for employees.
- In February 2015, the U.S. Department of Homeland Security's Customs and Border Protection (CBP) announced a pilot program to train and equip CBP officers with naloxone at seven ports of entry. Since then, CBP's naloxone program has gradually expanded. As of October 2016, CBP reports that officers are trained and equipped at 34 ports of entry. There are a total of 329 CBP-controlled ports of entry into the United States. A third phase of expansion or a permanent program is being considered for FY 2017, but will depend on funding. CPB officers are being trained to administer naloxone, but also CPR and AED use. Currently, the CBP naloxone program only includes the Office of Field Operations at the ports of entry, and has not been deployed to the Border Patrol or other CBP components. The officers are also being trained to use naloxone on themselves in case of inadvertent contact with fentanyl or other synthetic opioids in performance of their duties. To date, naloxone has not been used by a CBP officer in an overdose situation.
- During FY 2017, the US Marshals Service (USMS) will train and equip 75 Operational Medical Support Unit (OMSU) medics from districts across the nation on the use of Naloxone. USMS medics provide emergency medical care for all USMS employees,

protectees, law enforcement personnel assisting the USMS, and the public. The first phase of this initiative will begin in early January in Baltimore, MD. At the conclusion of this training 50 of the 75 Medics currently in the OMSU program will be trained to carry Naloxone. The remaining 25 Medics will receive training in May of 2017.

- Because fentanyl and its analogs pose a potential hazard, the National Institute for Occupational Safety and Health published guidance to help protect law enforcement, public health workers, and first responders who could unknowingly come into contact with these drugs in the line of duty.[38]
- In 2016, SAMHSA will provide a total of $12 million specifically to increase use of the overdose reversal drug naloxone. States can use these funds to purchase naloxone, equip first responders with naloxone, and provide training on other overdose death prevention strategies. The FY 2017 Budget will continue these investments and includes an additional $10 million to address opioid overdose in rural areas, including through expanding access to naloxone.
- The VA supports the Opioid Overdose Education and Naloxone distribution program to help Veterans at risk of an opioid overdose. This program is a key objective of VA's Opioid Safety Initiative (OPI). In the less than two years since the program was implemented, over 12,000 Veterans have received a naloxone kit, and there have been 141 reported reversals as of December 2015.
- In December 2015, the Indian Health Service and the Bureau of Indian Affairs announced a new partnership to reduce opioid-related overdoses among American Indians and Alaska Natives. In 2016, the more than 90 IHS pharmacies will dispense naloxone to as many as 500 BIA Office of Justice Services officers and will train these first responders to administer emergency treatment to people experiencing an opioid overdose.
- In September 2015, CDC launched a $20 million Prescription Drug Overdose: Prevention for States initiative in 16 States to expand their capacity to put prevention into action in communities nationwide and encourage education of providers and patients about the risk of prescription drug overdose. In 2016, the initiative received a further increase of $50 million dollars to expand these State prevention activities to a national scale.
- CDC launched the Prescription Drug Overdose: Data-Driven Prevention Initiative (DDPI) by awarding $18 million over a three-year project period to 13 States and the District of Columbia to support efforts to end the opioid overdose epidemic in the United States. This program helps States advance and evaluate their actions to address opioid misuse, abuse, and overdose.
- In 2016, CDC also provided funding for enhanced surveillance will assist States and key stakeholders in improving prevention and response efforts by providing more timely data on fatal and nonfatal opioid overdoses and in-depth information on risk factors. $12.8

million was awarded to 12 States to better track opioid-involved overdoses over a three-year project period.

- DOD is ensuring that opioid overdose reversal kits and training are available to every first responder on military bases and other areas under its control.

Supporting Recovery

- In 2014, SAMHSA established the Recovery Support Strategic Initiative. Its purpose was to promote partnering with people in recovery from mental and substance use disorders and their family members to guide the mental health and substance use disorder health systems and promote individual, program, and system-level approaches that foster health and resilience (including helping individuals manage symptoms, and achieve and maintain abstinence); increase housing to support recovery; reduce barriers to employment, education, and other life goals; and secure necessary social supports in their chosen community.
- The Department of Housing and Urban Development, in partnership with the U.S. Interagency Council on Homelessness and HHS, is identifying best practices to support individuals using MAT in programs funded through HUD's Homelessness Assistance Grants to promote replication of best practices throughout the country. HUD also will work with its Continuums of Care partners to help individuals with prescription opioid or heroin use disorders and use housing to support recovery.

SAMHSA offers a range of recovery services and supports that help people develop resiliency and recover from mental and/or substance use disorders, for example:

- *Recovery to Practice* helps mental/substance use disorder health and general health care practitioners improve delivery of recovery-oriented services, supports, and treatment.
- *Partners for Recovery* offers technical support and information to those who deliver services to people with substance use and co-occurring mental health conditions.
- *Projects for Assistance in Transition from Homelessness* provides formula grants to the states and territories to support community-based outreach, linkages to mental health and substance use disorder treatment, case management, and other support services to individuals who are experiencing homelessness, or at imminent risk of homelessness, and who have serious mental illnesses, with or without co-occurring substance use disorders.
- *Transforming Lives through Supported Employment* grant program enhances state and community capacity to provide and expand evidence-based, supported employment programs to adults with serious mental illnesses, including people with co-occurring mental and substance use disorders.

Research

The Administration continues to invest in substance use research and prevention programs. The NIH's annual funding for substance use treatment, substance use prevention, and screening and brief intervention for substance use totals over $1.7 billion per year.[39]

The Administration's BRAIN initiative supports research to develop methods for measuring and understanding the structure and functions of the brain at levels never before achieved. Such detailed measurement is necessary to understand the individual patterns of brain activity and impairment that are essential to the development of personalized interventions, and can offer promise for a range of illnesses, including substance use disorders.[40]

Because of these investments, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) research initiatives during the Obama Administration have produced exciting results such as:

- Research on opioids conducted and funded by HHS helps the department better track and understand the epidemic, support the development of new pain and substance use disorder treatments, identify evidence-based clinical practices to advance pain management, reduce opioid misuse and overdose, and improve opioid use disorder treatment – all areas of research that are critical to our national response to the opioid epidemic. In July 2016, HHS announced that it would launch more than a dozen new scientific studies on opioid misuse and pain treatment to help fill knowledge gaps and further improve our ability to fight this epidemic. As part of this announcement, the Department released a report and inventory on the opioid misuse and pain treatment research being conducted or funded by its agencies in order to provide policy-makers, researchers, and other stakeholders with the full scope of HHS activities in this area. The report will also help these stakeholders and external funders of research avoid unnecessarily duplicating research that is currently underway.
- FDA announced safety labeling changes for all immediate-release opioid pain medications, including requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose and death associated with these drugs. The Agency also issued a draft guidance intended to support the development of generic versions of abuse-deterrent opioids. Abuse-deterrent drug formulations are designed to make the drug more difficult to misuse, including making it harder to crush a tablet in order to snort the contents or more difficult to dissolve the product in order to inject it.
- Using its fast-track and priority review systems, FDA approved for the first time a nasal spray version of naloxone hydrochloride and a hand-held auto-injector that can be carried

in a pocket, providing two easy to administer ways to deliver this lifesaving drug. The National Institute on Drug Abuse helped develop the nasal spray through a partnership to apply new technology towards developing interventions for opioid overdose.

- The Collaborative Research on Addiction at NIH (CRAN), a partnership of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Cancer Institute, was established to advance research on substance use, misuse, and addiction. In 2015, CRAN and other NIH collaborators launched the Adolescent Brain Cognitive Development study, the largest long-term study of brain development and child health in the United States that will yield an unprecedented amount of information about how adolescent brain development is affected by alcohol and other substance use.
- DEA announced a policy change designed to foster research by expanding the number of DEA- registered marijuana manufacturers. This change should provide researchers with a more varied and robust supply of marijuana. As of the announcement in August 2016, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes. This change illustrates DEA's commitment to working together with the FDA and NIDA to facilitate research concerning marijuana and its components.[41]

In addition, the President's Precision Medicine Initiative was launched in 2015. Building on the $200 million investment in 2016, the President's Fiscal Year 2017 budget proposed a $100 million increase to develop a voluntary national research cohort of a million or more individuals to propel our understanding of health and disease and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing.

These examples represent only a few of the many advances in research achieved during this Administration.

Our Work Continues

The work throughout the Obama Administration is a powerful testament to the Administration's commitment to preventing and treating substance use disorders. Yet, there is more work to do to continue to advance the goal of quality, affordable, and accessible health care and public health for all Americans. Together with patients, consumer advocates, researchers, and health care professionals, we will continue to invest in, and work for, better prevention, detection, and

treatment for substance use disorders so that individuals affected by these conditions get the treatment they need, when they need it – allowing them to live healthy, productive lives.

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