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**AN UPDATE ON THE  
PRESIDENT'S COMMISSION ON  
COMBATING DRUG ADDICTION  
AND THE OPIOID CRISIS:  
ONE YEAR LATER**

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## HIGHLIGHTS

The Trump Administration has made tremendous progress towards the goals of the report of the President's Commission on Combating Drug Addiction and the Opioid Crisis. This progress includes:

- President Trump secured \$6 billion in funding over two years from Congress to fight the opioid crisis.
- The Trump Administration's ad campaign, conducted in partnership with the Truth Initiative and the Ad Council, has over 1 billion views, with 58% of young adults 18-24 aware of these ads.
- From the President's inauguration in January 2017 to February 2019, initial market data suggests that the total amount of opioids being prescribed monthly (by retail and mail-order pharmacies) has dropped by 34%.
- Under President Trump's watch, the Department of Justice (DoJ) is prosecuting more fentanyl traffickers than ever before - 40 times more in FY 2018 than in FY 2016.
- In 2017, DoJ indicted 2 Chinese nationals accused of shipping powerful synthetic opioids, manufacturing and shipping deadly fentanyl analogues and 250 other drugs to at least 25 countries and 37 states.
- Through DoJ's Joint Criminal Opioid Darknet Enforcement, Federal enforcement is disrupting online illicit opioid sales; the initiative was responsible for 10 of the 13 Federal Bureau of Investigation darknet investigations in FY 2018.
- During President Trump's first full fiscal year in office (FY 2018), Immigration and Customs Enforcement's Homeland Security Investigations made 722 arrests and seized 2,208 lbs. of fentanyl, enough to kill every man, woman and child in America -- a 370% increase over 2 fiscal years (since FY 2016).
- Since the President took office, the number of patients receiving buprenorphine (one form of medication-assisted treatment) increased 23 percent, while the number of prescriptions for naltrexone (another form of medication-assisted treatment) increased 42 percent.
- From January 2017 through February 2019, the number of naloxone prescriptions dispensed has increased 484%.
- By partnering with the private sector, the Trump Administration is working to ensure that naloxone will be accessible at every YMCA, public library, high school, community college, and university in the country.
- The Trump Administration has invested \$500 million dollars in the HEAL Initiative, to bring new, non-addictive pain management therapies to patients in need.

## INTRODUCTION

The President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) was established by Executive Order on March 29, 2017. The Commission issued an interim report during the summer with nine recommendations and its final report on November 1, 2017. The final report not only brought needed attention to the crisis, but also included 56 additional recommendations that fell broadly into nine overarching goals. In the year following this report, the Trump Administration is pleased to announce there has been extraordinary progress made toward achieving these goals.

President Trump's *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* focused on ending the crisis through a multi-pronged approach aimed at reducing drug demand, cutting off the flow of illicit drugs, reducing overdose deaths, and expanding access to evidence-based treatment. The President's Initiative, coupled with the Commission's recommendations, helped galvanize Federal, state and local governments to address this crisis in an unprecedented way. The effort included record new funding and culminated with President Trump signing the most comprehensive drug control legislation in our Nation's history, the *Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (herein referred to as the SUPPORT Act). The progress achieved in the last year will help lay the foundation for ending this deadly public health crisis.

### **I. BREAK DOWN SILOS AND BUREAUCRACY TO GET FEDERAL FUNDING TO STATES THAT ARE ON THE FRONT LINES OF FIGHTING THE EPIDEMIC**

To respond effectively to the opioid crisis, states must be able to obtain Federal resources specific to their needs with minimal bureaucratic delay and administrative burden. State, local, and tribal governments must also have the flexibility to decide how best to use these resources in their diverse communities. Therefore, in order to develop these tailored, community-level responses to the crisis, President Trump's Administration adopted a grant funding mechanism for the three largest programs established expressly for addressing the opioid crisis: the State Targeted Response to the Opioid Crisis (Opioid STR), State Opioid Response (SOR), and Tribal Opioid Response (TOR) programs. In 2017, the Substance Abuse and Mental Health Services Administration (SAMHSA) awarded \$2.4 billion to states through the Substance Abuse Prevention and Treatment (SAPT) Block Grant and the Opioid STR program to address substance use disorders, including opioid use disorders. This funding was in addition to SAMHSA discretionary grants and the treatment funding available through Medicaid and Medicare. In 2018, building on the prior year's efforts, SAMHSA awarded \$3.4 billion in combined SAPT funding, second year STR continuation grants, and first-year awards for the SOR and TOR grant programs. Also in 2018, SAMHSA awarded an additional \$16 million in grants to support a new model of training and technical assistance capitalizing on the use of local expert teams in each state, for STR grantees. All of these efforts, which together with other efforts total a record \$6 billion in new funding to address this crisis, highlight President

Trump's commitment to pursuing creative solutions to ensure resources are efficiently delivered while also maintaining flexibility for states.

Further, to streamline and facilitate a flexible whole-of-government approach to the crisis, President Trump's Administration directed the Department of Health and Human Services (HHS) Secretary to declare the opioid crisis a Public Health Emergency in October 2017. This declaration was historic because it was the first time the Federal Government has tapped the emergency authorities under the Public Health Service Act to help address a public health crisis related to substance use. Under the declaration, all Federal executive agencies are able to use every appropriate emergency authority they possess to combat the crisis, including streamlining government activities and reallocating staff.

In addition, the Office of National Drug Control Policy (ONDCP), through its Demand Reduction Executive Steering Group and the interagency work groups (IWGs), has spearheaded efforts to coordinate a centralized response to the opioid crisis across Federal agencies, including the recent establishment of a Rural Opioid Response IWG. Overall, the Administration has made significant strides in delivering resources and will continue to pursue initiatives that address the crisis in the most efficient way.

## **II. COLLABORATE WITH STATES, PRIVATE SECTOR PARTNERS, AND OTHER STAKEHOLDERS TO ENHANCE AWARENESS AND SCREENING EFFORTS TO PREVENT INAPPROPRIATE USE OF OPIOIDS AND OTHER DRUGS**

Enhancing awareness and screening efforts to prevent prescription drug misuse, illicit drug use, and addiction are critical components to address in this crisis. Thus, since the Commission's recommendations were finalized, the Administration has developed and launched a national media campaign, promoted screening and evidence-based prevention, and taken steps to better inform patients about the risks of opioid medications.

In June 2018, the Administration launched a series of public awareness advertisements to combat the opioid crisis. A second round of prevention ads were released in October 2018. Shown on television, targeted social media and on-line platforms, these ads are based on the real-life experiences of people affected by addiction and are specifically aimed at preventing young adults from misusing prescription opioids or using illicit opioids. These are the first of many ad campaigns through which the Administration will target key audiences and various aspects of the opioid crisis.

Recognizing the value of early intervention and treatment for individuals with substance use disorders, the Administration has promoted the adoption of the Screening, Brief Intervention and Referral to Treatment (SBIRT) protocol in diverse health care and academic settings. SBIRT is an evidence-based approach for delivering early intervention and treatment to people with substance use disorders and identifying those at risk of developing these disorders. The Health Resources and Services Administration (HRSA) provides training and technical assistance to support SBIRT adoption across the nation in HRSA-funded

Community Health Centers. In September 2018, HRSA awarded \$350 million to 1,232 Health Centers to increase access to mental health and substance use disorder services across the nation. The Administration also supports SBIRT adoption through its Adolescent and Young Adult Health National Resource Center, its Bright Futures Pediatric Implementation program, the Collaborative Improvement and Innovation Network on School-Based Health Services, and the Rural Health Opioid Program.

SAMHSA has expanded the implementation of SBIRT in settings such as primary care centers, hospital emergency rooms, trauma centers and other community settings. This allows for early intervention opportunities for those most at-risk for substance abuse to get the care they need before more severe consequences occur. Additionally, SAMHSA's Prevention Technology Transfer Centers' (PTTC) network provides training, technical assistance, and academic programs to communities with the goal of identifying best practices for preventing substance misuse, including opioids. SAMHSA's Addiction Technology Transfer Center (ATTC) program also provides early intervention and SBIRT training to practitioners across the healthcare field, and has instituted a tailored partnership with the Centers for Disease Control and Prevention (CDC) to provide specific SBIRT training to practitioners treating those living with HIV.

CDC's opioids effort, Overdose Prevention in States (OPIS), includes three programs that equip states with resources needed to address the epidemic. The three programs are Prescription Drug Overdose: Prevention for States (PFS), Data-Driven Prevention Initiative (DDPI), and Enhanced State Opioid Overdose Surveillance (ESOOS). The resources and information from these programs help combat prescription and illicit opioid abuse and overdose and is the heart of the CDC's work on this epidemic. As of September 2018, CDC is funding at least one program in all 50 states, Washington, D.C., and four territories.

Informing patients about the risks associated with prescribing opioids, even when prescribed by a health professional, is a serious issue engaging this Administration. The Department of Defense (DoD) requires a Military Health System to standardize Opioid Therapy Informed Consent, and the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) requires patients to be educated about side effects, risks, and alternatives to taking opioid medication long-term. Also at the VHA, informed consent is documented before opioid therapy is used for 90 days or longer and adherence to this directive is tracked. Further, the Indian Health Service's (IHS) Indian Health Manual focuses on "Chronic Non-Cancer Pain Management," which requires all patients started on non-cancer chronic pain management with an opioid medication to have a signed informed consent on file that explains the risks, benefits, and alternatives to opioid therapy. Meanwhile, the Department of Labor (DOL) has undertaken a more targeted approach by sending individualized letters to claimants and their medical providers discussing their current use of prescription opioids for the treatment of pain. DOL has also used targeted mailings to inform claimants of risks associated with opioid prescription use.

*Take Back Day* events have also been a great opportunity for the Trump Administration to educate and raise awareness of the prescription drug crisis and remind the public of the importance of properly disposing of unused, expired, and unwanted prescription medications. These events, which often involve several agencies, not only remove dangerous drugs from circulation, but they have the potential to offer screening opportunities and potential linkage to treatment at the event site. As part of its *Take Back Day* program, the Drug Enforcement Administration (DEA) educates communities on the importance of screening and treatment and the proper disposal of unused and unwanted prescriptions. As a result, both the April 28 and October 27 *Take Back Day* events in 2018, conducted by the DEA, each resulted in the collection of nearly one million pounds of unwanted drugs. To date, the Trump Administration has collected over 3.7 million pounds of unwanted drugs and added nearly 500 additional collection sites.

In an effort to facilitate safe disposal of these drugs, the DEA encourages its registrants to become “authorized collectors” pursuant to a final rule entitled, “Disposal of Controlled Substances.” This regulation implements the Secure and Responsible Drug Disposal Act of 2010 and expands on the previous methods of disposal by including disposal drop-boxes in pharmacies and law enforcement agencies, mail-back programs, and drug deactivation systems that render the product irretrievable. As of October 2018, there are over 5,000 DEA registered collectors, who have become “authorized collectors” so they can offer takeback in pharmacies or eligible hospitals.

### **III. MAXIMIZE THE USE OF PRESCRIPTION DRUG MONITORING PROGRAMS THROUGH BETTER DATA INTEGRATION AND UTILIZATION**

The Administration recognizes that effective Prescription Drug Monitoring Programs (PDMPs) are essential to overcoming the opioid crisis. In fact, the *President’s Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* includes, as a key objective, leveraging Federal funding opportunities to ensure states transition to a nationally interoperable PDMP network. During the past year, the Administration has worked in a coordinated effort with Federal agencies and states to strengthen these programs in order to prevent prescription drug misuse and the issues associated with it.

PDMPs are electronic databases that collect and store information about controlled substance dispensing records. Authorized medical professionals can query the PDMP to understand patient controlled prescription drug use patterns across all participating facilities. States generally authorize and maintain PDMPs, and providers may interact with other state’s PDMPs through a data sharing system called a hub. Currently, 49 states have PDMPs and the VA, through its own PDMP network, has conducted over 2.3 million queries to state PDMPs. The information contained in PDMPs is extremely important to identify high-risk patients in order to provide them the necessary help to either prevent or treat addiction before it threatens their lives.

DoJ's Bureau of Justice Assistance (BJA) currently provides funding to support one of two interstate data-sharing hubs in existence. BJA's hub, known as RxCheck, is an open-standards solution developed and operated in partnership with the Integrated Justice Information Systems Institute. The second hub is operated through a private vendor. As of January 2019, 16 states are active or are implementing interstate data-sharing using both hubs, 32 states and the District of Columbia are active or in the process of are implementing interstate data-sharing using the private vendor hub only, and two states are active or are implementing interstate data-sharing using the RxCheck hub only.

In an effort to integrate PDMP data with electronic health records (EHRs), the Office of National Coordinator for Health Information Technology (ONC) worked with the National Council for Prescription Drug Programs to modify prescription standards in order to support data integration across EHRs and pharmacy systems. Additionally, ONC developed an implementation guide to more easily allow access to PDMP data for a patient from a state PDMP system. This ensures more providers can better access PDMP data through their regular clinical workflow.

The Administration has also been working with states to integrate PDMP data with hospital EHR platforms so they can easily check PDMPs in order to learn the patient's prescribing history if the patient is treated for an overdose. Likewise, the Administration has supported the States' use of PDMPs to monitor naloxone administration in order to monitor not only patients' prescription history, but overdose history as well.

While PDMPs are critical to mounting an effective response to the opioid crisis, the Administration recognizes that ongoing surveillance data collection and analysis are also important. There has been a concerted Federal effort to strengthen data collection to permit real-time surveillance of the opioid crisis. For example, ONDCP supports the Overdose Detection Mapping Application (ODMAP), which provides real-time overdose surveillance data across jurisdictions to support efforts to mobilize immediate public health and public safety responses to an overdose spike. ODMAP links first responders on scene to a mapping tool to track overdoses to permit real-time response and strategic analysis across jurisdictions. In addition, CDC's ESOOS program provides funds to states to increase the timeliness and comprehensiveness of data on non-fatal overdoses and risk factors associated with fatal overdoses. These programs, in conjunction with the effective use of PDMPs, are playing a vital role in the Trump Administration's efforts to end the opioid crisis.

#### **IV. ENHANCE EDUCATION AND TRAINING FOR MEDICAL PROFESSIONALS TO REDUCE INAPPROPRIATE PRESCRIBING**

President Trump's *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* includes the goal to decrease opioid prescriptions by one-third over three years. To accomplish this objective, it is imperative that medical professionals are educated and trained on opioid prescribing and opioid alternatives, as well as ensuring the Federal

government takes part in developing best practices, guidelines, and training material to assist prescribers. Due to many of the efforts highlighted below, the total amount of opioids being prescribed fell by 34% from January 2017 through February 2019, according to initial market data.

Many of the HHS components were integral in developing and delivering enhanced training and education in these domains. For example, the Centers for Medicare and Medicaid Services (CMS) has developed resources and learning opportunities for states and providers on managing opioid prescribing and implementing the CDC Guideline for Prescribing Opioids for Chronic Pain. In addition, IHS, through the Indian Health Manual, now requires its prescribers to complete safe opioid prescribing training at on boarding and to repeat this training every three years. This comprehensive policy also establishes best practice requirements surrounding chronic opioid therapy.

The Food and Drug Administration (FDA) has been a leader in developing approaches to reduce opioid prescribing. In September 2018, the FDA released a new, broadened Opioid Analgesics Risk Evaluation Mitigation Strategy (REMS). The new REMS covers immediate-release opioid analgesics intended for use in outpatient settings and, for the first time, makes training available to health care professionals involved in the management of patients with pain including physicians, nurse practitioners, physician assistants, nurses, and pharmacists. As part of the new Opioid Analgesics REMS, FDA issued a revised Blueprint for health care provider education. The Blueprint, “Opioid Analgesics REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain,” conveys core educational messages for prescribers and other health care providers involved in the treatment and monitoring of patients with pain, including information on pain management strategies, and pharmacologic and non-pharmacologic treatments for pain.

The Blueprint also provides information about addiction medicine, opioid use disorder, and the distinction between physical dependence, tolerance, and addiction. The REMS requires manufacturers of extended-release, long acting, and immediate-release opioid analgesics to make training available to health care providers based on the Blueprint. Additionally, through the recently enacted *SUPPORT for Patients and Communities Act* (SUPPORT), FDA received authority to constrain certain risky products using packaging to limit prescribing duration. When FDA implements this new authority, prescriber training materials will address packaging and the typical dose duration for specific conditions.

CMS has made significant progress in identifying overprescribing patterns and is building on the CDC Guideline for Prescribing Opioids for Chronic Pain to help reduce prescription opioids and the associated risk of iatrogenic harm, such as overdose, or development of opioid use disorder. For instance, it requires all Medicare Part D sponsors to develop a written strategy for addressing overutilization of prescription opioids. CMS is also working with state Medicaid programs to reduce overprescribing of prescription opioids through practices such as step therapy, prior authorization requirements and limits on the



quantity of opioids the program will cover. In the President's FY 2019 Budget, CMS proposed establishing minimum standards for the Medicaid State Drug Utilization Review program, a tool it uses to oversee state activities in this area. CMS will continue to work with states to implement additional drug utilization review requirements.

Educating practitioners on the risk of opioid diversion is of particular importance to the Administration. DEA has been hosting Practitioner Diversion Awareness Conferences for people registered to prescribe and dispense controlled substances. These include pharmacists, dentists, nurse practitioners, physicians, physician assistants, and veterinarians who have a DEA registration to prescribe, administer, and/or dispense controlled substances in their state. The objective of these conferences is to educate practitioners on diversion and prescribing practices that could result in DEA investigatory enforcement actions. The DEA is aiming to hold conferences in all 50 states.

In addition to educating medical professionals on the significance of decreasing unnecessary opioid prescribing, HHS is also ensuring there are not financial or other incentives to prescribe opioids to achieve high customer satisfaction ratings. Through the recently enacted SUPPORT Act, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey will no longer include questions about a patient's level of satisfaction with how well providers managed their pain, unless the patient is informed about the risks of opioids and about non-opioid alternatives for pain management. In compliance with this provision, in recent rulemaking related to outpatient hospitals, CMS removed the HCAHPS pain questions effective October 1, 2019, for the 2020 payment determination.

It is also imperative to properly train and educate medical professionals and first responders in the field who continue to risk their lives each day to respond to these record numbers of overdoses. The increased prevalence of fentanyl and other synthetic opioids in the illicit drug market requires first responders to understand how to protect themselves from exposure in the field. In August, the Administration released a training video on Fentanyl Safety Recommendations for First Responders that provides unified, evidence-based instructions to first responders so they can better protect themselves when the presence of fentanyl is suspected. The training video was based on the Administration's Fentanyl Safety Recommendations fact sheet to help educate First Responders. Similarly, the Department of Homeland Security (DHS) Office of Health Affairs produced a training document for DHS first responders on the safe handling of fentanyl. All of these efforts demonstrate a coordinated and committed approach to first responder training.

## **VI. STRENGTHEN LAW ENFORCEMENT EFFORTS TO TARGET AND TAKE DOWN INDIVIDUALS AND ORGANIZATIONS THAT PRODUCE AND SELL COUNTERFEIT OR ILLICIT DRUGS**

Throughout the past year, the Trump Administration has intensified the Federal government's development of new cutting-edge interdiction methods, placing a special focus on the cyber technologies needed to strengthen law enforcement's efforts to track, disrupt, and seize the financial vehicles used to fund the drug trade. In addition, the Administration has targeted both large and small-scale traffickers involved in the distribution of illicit fentanyl and its analogues by vigorously investigating and prosecuting those involved in its sale and production.

Opioid interdiction has become more challenging with the increased use of mail and express consignment, which are used to deliver illicit opioids directly to drug users and small-scale distributors in the United States. The Administration has responded with a multi-faceted effort designed to combat the traditional methods of distribution and the use of the U.S. postal system. HHS, including its FDA, has been working with U.S. Customs and Border Protection (CBP) and other partners to identify shipments of counterfeit or diverted drugs being mailed to and billed by providers enrolled in HHS programs.

Demonstrating the Administration's robust commitment to law enforcement, in 2018 the Attorney General announced the largest health care fraud and opioid enforcement action in history. As part of this initiative, a total of 601 defendants were charged across 58 Federal districts. This included 165 doctors, nurses, and other licensed medical professionals for their alleged participation in health care fraud schemes involving more than \$2 billion in fraudulent billings. Additionally, 162 of these defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics. This action involved a coordinated effort involving 30 state Medicaid Fraud Control Units. Additionally, since July of 2017, HHS has excluded approximately 600 providers participating in Medicaid and Medicare for conduct related to opioid diversion and abuse, and the FDA sent enforcement letters to networks responsible for operating 53 websites marketing unapproved opioids as part of a comprehensive effort to target online sales.

The financing of drug trafficking organizations (DTOs) has been transformed by the rise of virtual currencies used to facilitate the drug trade over the internet on both the dark and clear web. The use of virtual currency has created the need for more sophisticated investigative techniques, both on the drug distribution and the financial side of drug trafficking organizations. In response, the Administration has focused significant resources and efforts on cyber enforcement. As part of this effort, DEA developed a Virtual Currency Initiative, focused on the identification, disruption and dismantlement of major domestic and foreign DTOs that utilize the clear and dark web for the distribution of controlled substances and the laundering of drug proceeds. The DEA developed a Cyber Investigations Course to equip agents and analysts with the resources needed to battle online opioid traffickers. The

DEA also maintains a Financial Operations Section to assist agents in identifying and seizing assets and drug proceeds stored in cryptocurrency wallets.

The U.S. Postal Inspection Service (USPIS) and the Federal Bureau of Investigation (FBI) have been actively involved in the fight. With 353 investigations linked to dark web and illicit drug vendors, USPIS regularly partners with Federal, state, local, and tribal law enforcement to conduct investigations. The creation of the FBI's Joint Criminal Opioid Darknet Enforcement (J-CODE) team in January 2018 directly targeted drug trafficking, especially fentanyl and other opioids, on the Darknet. With this team, the FBI is now bringing together agents, analysts, and professional staff with expertise in drugs, gangs, and health care fraud, and Federal, state, and local law enforcement partners from across the U.S. Government, to focus on disrupting the sale of drugs via the Darknet and dismantling criminal enterprises that facilitate this trafficking. With these and other measures, the Administration has demonstrated a steadfast commitment to ensuring enforcement is in step with the changing times.

The Administration recognizes that while interdicting illicit opioids is important, it is equally important to hold accountable those involved in prescription opioid overprescribing, fraud, and diversion. In August 2017, the Attorney General announced the creation of the Opioid Fraud and Abuse Detection Unit, a new DoJ analytics program focused on identifying opioid-related health care fraud and medical providers who are contributing to the opioid crisis. The unit coordinates Federal data by reviewing information from HHS and DEA and providing it to United States Attorneys for use in investigations. This data identifies physicians who are writing opioid prescriptions at rates far exceeding their peers and pharmacies that are dispensing disproportionately large amounts of opioids in regional hot spots of opioid misuse and abuse. Additionally, the Attorney General assigned experienced prosecutors to focus solely on investigating and prosecuting opioid-related healthcare fraud cases in high-risk districts who are working with the FBI, DEA, HHS, and state and local partners to specifically target drug diversion. To date, \$3.3 billion has been recovered from these efforts.

One of the most daunting trends has been the proliferation of fentanyl and fentanyl analogues, which have the potential to be exponentially more lethal than other opioids. In order to address this, the Trump Administration has prioritized the investigation and prosecution of individuals and organizations that deal in these particularly lethal substances in a number of ways. First, the Administration has supported increased penalties for those involved in the distribution of fentanyl and legislation designed to increase its detection. Second, the DEA has made fentanyl investigations a priority. DEA's Special Testing and Research Laboratory, along with CBP chemists, are analyzing over 200 fentanyl and fentanyl analogue exhibits with the goals of ascertaining the source of the drugs and linking seizures through common forensic attributes. Third, in an effort to address fentanyl in counterfeit pill form, the DEA Diversion Control Division has created the National Tablet and Encapsulating Machine Initiative to identify local distributors and DTOs that use tableting machines to

manufacture illicit drugs. The National Security Council has been actively involved in educating first responders and law enforcement on the safe handling of fentanyl. While the challenges posed by fentanyl are significant, the Administration is poised to effectively deal with them as part of a comprehensive approach to ending the opioid crisis.

During the G20 Leaders Summit in December 2018, President Trump made a strong case for China to designate all fentanyl as a controlled substance. China's President Xi pledged to do that, giving Chinese law enforcement the legal and regulatory framework to pursue manufacturers and distributors of this harmful drug. In addition, given that 40 forms of fentanyl and synthetic opioids have been reported across 37 countries, this Administration is working with international partners to stop drug traffickers. 131 countries have joined President Trump's Global Call to Action, and are developing their own comprehensive strategies to tackle drug trafficking.

## **VI. ENHANCE EFFORTS TO DETECT AND INTERCEPT ILLICIT DRUGS COMING ACROSS OUR BORDERS**

Strengthening our nation's borders is crucial to ending the opioid crisis. Most of the heroin and illicit fentanyl in the United States is of foreign origin, with over 90% of the heroin coming from Mexico and the majority of illicit fentanyl coming from China. Through technology for detection and identification, the Trump Administration has made significant strides to strengthen our borders, ports, and international mail facilities to stem the flow of illegal drugs.

The Administration recognizes that in order to curb the flow of illicit opioids coming into the country, it must use cutting edge technology to detect these drugs and readily adapt its availability reduction capabilities to the dynamics of drug trafficking. USPIS has partnered with other Federal law enforcement agencies to reduce the amount of drugs and illicit substances entering the United States through domestic and international mail. As part of this effort, the USPIS, the DEA and DHS are better integrated to ensure intelligence, seizure data, and other sensitive information are shared in a timely manner.

USPIS's efforts have yielded promising results in the interdiction of drugs and the prosecution of those involved in producing, distributing, or trafficking them. In 2017, USPIS initiated 2,196 illicit drug cases which resulted in 1,954 criminal convictions. In the first year of the Trump Administration, USPIS achieved a 375% increase in drug seizures from international parcels and an 880% increase in domestic parcel seizures related to opioids. To more effectively address illicit internet drug sales, USPIS recently launched a Cyber and Analytics Unit, which enhances investigative techniques and analytics to better forecast and target international parcels. USPIS is upgrading its technological capabilities in collaboration with CBP to further assist in detecting narcotics in the mail.

The United States Postal Service (USPS) has substantially increased its use of Advanced Electronic Data (AED) over the past two years by prioritizing data from the largest

volume foreign postal operators, which collectively account for over 90% of all inbound parcels. To date, there has been a 34% increase in AED on all incoming parcels since August 2017. AED is information collected by USPS to identify incoming shipments for advance targeting based upon intelligence, prior violations, and other risk factors. The *Synthetics Trafficking and Overdose Prevention Act* (STOP Act) of 2018, which was part of the SUPPORT Act, mandates the transfer of AED information on Postal shipments. Additionally, USPS adopted a policy requiring AED to accompany any package covered by a bilateral agreement with foreign postal operators, including China.

AED Sharing Agreements have been executed with a majority of foreign postal operators, as USPS strives to make AED exchanges the standard in cross-border postal operations. USPS accelerates AED collection through its Global Direct Entry (GDE) Wholesaler Program. Private sector companies participating in GDE are required to provide inbound international shipments with AED to CBP, which significantly increases the success of interdiction. Recognizing the challenges of detecting small amounts of illicit fentanyl in packages coming to the United States through the mail, our ports, and our land borders, CBP implemented a Canine Fentanyl Detection Pilot Course with its first canine detection teams graduating in November 2017. The trainings are ongoing and to date approximately 460 dogs trained to detect fentanyl are assigned to U.S. ports of entry.

In addition to these Federal law enforcement efforts, the White House, through legislation and efforts from offices within the Executive Office of the President, has demonstrated an unwavering commitment to ensuring Federal law enforcement keeps pace with criminal organizations attempting to bring illicit drugs into the country and individuals purchasing the illicit substances on the internet for small scale distribution or person use. On January 10, 2018, the President signed the *International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology* (INTERDICT) Act, providing \$9 million for chemical screening devices, personnel and scientists to prevent, detect and interdict the unlawful importation of illicit fentanyl, fentanyl analogues and other synthetic opioids. ONDCP has partnered with DHS and USPIS to sponsor a global Prize Challenge seeking technology to detect fentanyl in international mail and express consignment parcels. The competition will award \$1,550,000 to the best candidates. All of these efforts illustrate the Trump Administration's pursuit of creative and innovative, whole-of-government solutions to the opioid crisis.

## **VII. EXPAND ACCESS TO EVIDENCE-BASED TREATMENT AND RECOVERY SERVICES BY REVISING REIMBURSEMENT POLICIES FOR FEDERAL PAYERS AND ENSURING PRIVATE PAYERS ARE COMPLYING WITH THE LAW**

The Administration has prioritized increasing access to evidence-based treatment, such as medication-assisted treatment (MAT), and recovery services by improving quality measures for these services, expanding treatment and referral to care, and addressing payment and policy barriers.

To improve quality measures, CMS included provisions in the 2019 Core Set of Adult Health Care Quality Measures for Medicaid to ensure individuals diagnosed with a substance use disorder (SUD) receive proper follow-up and treatment services. To improve treatment and make appropriate referrals, HHS promoted increased screening for SUDs and referrals to specialty care when needed through several of its programs.

Telemedicine is another tool the Administration is leveraging to increase access to evidence-based care. Telemedicine allows for two-way, real time interactive communication between a medical professional and a remote patient or between medical professionals, making care less expensive and more accessible in rural communities. The Administration has supported the use of telemedicine on a number of fronts to increase access to effective care. For instance, the HRSA recently awarded grants to expand and/or increase the breadth of services available through successful telehealth networks through its Substance Abuse Treatment Telehealth Network Grant Program. The purpose of this program is to demonstrate how telehealth programs and networks can improve access to health care services, particularly substance abuse treatment services, in rural, frontier, and underserved communities. In the recent Medicare Physician Fee Schedule rule, CMS finalized a policy to increase payment for use of telecommunications technology between patients and physicians. Titles II and VII of the SUPPORT Act also promotes the use of telemedicine so more people can have access to evidence-based treatment –particularly in hard-hit rural communities.

To ensure rural communities are getting the needed resources, the United States Department of Agriculture (USDA) partnered with ONDCP to establish the Rural Opioid Response Interagency Working Group (IWG) focused on coordinating efforts and resources for rural communities. Through the Rural Opioid Response IWG, USDA and local leaders lead a monthly forum for rural stakeholders to share information and develop collaborative solutions. In collaboration with ONDCP, USDA also worked with Federal Partners to develop a guide to Federal resources for rural communities to access. Additionally, USDA has worked with Federal Partners to develop the Community Assessment Tool that helps local leaders identify the factors that may drive the opioid crisis in their individual communities. To better inform these communities, USDA has added an opioids resource webpage on its website to provide information about programs and model prevention, treatment, and recovery practices in each state.

Additionally, through the USDA Distance Learning and Telemedicine Grant Program, the USDA also helped rural leaders in 68 communities in 33 states access treatment, counseling services, and prevention education through remote connections and provided grant assistance for facilities, vehicles and equipment to expand access to mental and behavioral health care and improve public safety for 85 communities in 22 states. USDA prioritizes telemedicine project applications that have the primary purpose of providing opioid misuse prevention, treatment, or recovery services to rural individuals.

Recognizing that screening for SUD is crucial before providing evidence-based treatment, the VA has established a comprehensive process for SUD screening and referral for misuse of alcohol and tobacco, prescription drug misuse, and illicit drug use. Both the VA and the DoD, in collaboration with other professional organizations, have developed clinical practice guidelines to guide the management of SUDs, including opioid use disorders (OUD), across the VHA and DoD. VHA's integrated system of care provides both formal and informal support and consultation to providers along with access to SUD treatment. In support of recommendations from the Commission's report and as part of efforts to improve access to care, VHA is working to expand current consultation and training supports through its MAT Initiative as well as the implementation facilitation phase of Stepped Care.

In an effort to ensure all veterans receive proper care, VA's deployment of Stepped Care for OUD protocols provides another mechanism for ensuring access to MAT at the least restrictive level of care. It provides access to those at the highest risk for opioid-related adverse events in settings where they are already receiving care. In August 2018, the VA held a train-the-trainer conference focused on expanding Stepped Care for OUD. The VA-wide effort provided knowledge and action planning for the stepped care treatment model for designated pilot teams within each Veterans Integrated Service Network. Also in 2018, VHA initiated same-day access for withdrawal management and outpatient SUD specialty care for all veterans. VHA will continue to expand efforts to provide timely access for MAT, intensive outpatient treatment, and, when needed, residential treatment for veterans diagnosed with an OUD. In addition, VHA is working to ensure the consistent availability of MAT at the facility level and address any unintentional barriers.

There have been additional programs designed to remove financial barriers to evidence-based treatment. The CMS Innovation Center continues to work to develop and test several new delivery and payment models to incentivize the provision of evidence-based treatment. These models have robust quality measures that align with other Federal agencies' measurement strategies thus, providing an opportunity to aggregate or compare data across programs in order to more accurately measure processes and generate critical evidence linking these measures to payment and utilization outcomes. CMS is also working to implement the new bundled payments for opioid use disorder treatment services provided at Outpatient Treatment Programs under Medicare Fee-for service as required by the SUPPORT Act. Most recently, CMS announced the Integrated Care for Kids (InCK) Model, a child-centered local service delivery and state payment model aimed at reducing expenditures and improving the quality of care for children covered by Medicaid and the Children's Health Insurance Program through prevention, early identification, and treatment of priority health concerns including SUD and mental health challenges.

Providing the necessary treatment for pregnant mothers with an opioid use disorder is vital for the health of both the mother and the baby, as championed by First Lady Melania Trump through her Be Best initiative. In an effort to provide the most effective treatment, CMS recently announced the Maternal Opioid Misuse (MOM) model, which will work with

state Medicaid agencies to provide a wide range of integrated services for pregnant mothers struggling with OUD, including prenatal care, OUD treatment and referrals to social services. The model improves the targeting and coordination of care for pregnant and postpartum Medicaid beneficiaries with OUD through state-driven transformation of the delivery system surrounding this vulnerable population. By supporting the coordination of clinical care and the integration of other services critical for health, wellbeing, and recovery, the MOM model has the potential to improve quality of care and reduce expenditures for mothers and infants.

A significant policy barrier addressed in the President Trump's *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* is the IMD (Institutions for Mental Diseases) exclusion, a provision of the Social Security Act enacted in 1965 that was originally designed to prevent the warehousing of persons with mental illness. This decades old IMD exclusion prohibits Medicaid from reimbursing residential treatment at certain facilities with more than 16 beds. To address reimbursement issues for treatment in larger SUD treatment facilities, in November 2017, CMS announced a new direction through a State Medicaid Director letter, creating a more flexible, streamlined approach to accelerate states' ability to cover SUD treatment in residential facilities that qualify as IMDs, as long as the state takes specific steps to ensure quality of care in these facilities and maintain the availability of non-institutional community-based care. Through these Section 1115 SUD demonstration projects, CMS worked with the states to facilitate access to MAT and ensure appropriate utilization management approaches for ensuring timely screening, referral, and placements based on medical necessity. To date, CMS has approved nineteen 1115 state demonstration waivers and nine more are under review.

Notably, the recently enacted SUPPORT Act temporarily removes the IMD exclusion for certain IMDs for treatment of qualified individuals. However, the IMD must make specified assurances to the state about maintenance of effort and evidence-based care, including MAT. By allowing for payment in IMDs for eligible individuals, state Medicaid programs may receive Federal reimbursement for up to 30 days total of care in an IMD during a 12-month period for eligible individuals. While CMS works to implement this provision, it will continue to approve 1115 state Medicaid demonstration waivers through the November 2017 State Medicaid Director Letter.

As mentioned, the Administration is committed to increasing access to care via telehealth. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 aims to prevent illegal distribution and dispensing of controlled substances through the internet, but can be an obstacle to prescribing MAT via telemedicine because of the requirement for an in-person visit with a trained provider. IHS recently clarified exceptions provided under the Ryan Haight Act to the in-person evaluation requirement through release of the IHS Internet Eligible Controlled Substance Provider Designation policy. The policy enables IHS, tribal, and urban Indian organization health care providers to apply to be designated by IHS as Internet Eligible Controlled Substance Providers, and is intended to expand access to tele-MAT models in rural and remote American Indian and Alaska Native communities. Additionally, in



May 2018, DEA issued guidance on proper use of telemedicine for the treatment of opioid use disorder in the context of the Ryan Haight Act and in September of 2018, HHS amplified the guidance with a document entitled, “Telemedicine and Prescribing Buprenorphine for the Treatment of Opioid Use Disorder.”

A strong provider workforce is needed to increase access to evidence-based treatment and recovery support services. Currently, HRSA is working to address the health workforce through a wide range of programs, including training and provider recruitment for workforce expansion and training and technical assistance to existing providers. The Health Center Program increased the number of clinicians eligible to provide MAT by 75 percent (from 1,700 in 2016 to 2,973 in 2017) and the number of patients receiving MAT by 64 percent (from 39,375 in 2016 to 64,597 in 2017). The HRSA Rural Health Opioid Program provides support to community consortiums in rural communities to prepare individuals with opioid use disorder to begin treatment, implement care coordination practices, and support individuals in recovery by establishing new or enhancing existing behavioral counseling, peer support, and alternative pain management.

In September of 2018, HRSA awarded an additional \$18.5 million in grants to support its Behavioral Health Workforce Education and Training and Enhancing Behavioral Health Workforce programs. These awards support partnerships between 21 academic institutions and 54 HRSA-funded health centers. Together, these award recipients will increase the number of professionals and paraprofessionals who are trained to deliver integrated behavioral health and primary care services as part of health care teams in HRSA-supported health centers. Similarly, the National Health Service Corps supports a student loan repayment program for SUD professionals who are working in underserved areas to address the shortage of workers in the substance use disorder field.

Finally, barriers to accessing MAT may exist due to a patient’s inability to obtain a prescription for buprenorphine or naltrexone (two types of MAT) at a pharmacy. To address this issue, in August 2018, IHS added buprenorphine, combination buprenorphine/naloxone, and naltrexone to the National Core Formulary, which requires all IHS Federal pharmacies to stock these MAT medications and dispense these medications pursuant to a valid prescription from an authorized prescriber. All of these efforts demonstrate the Administration’s commitment to increasing access to evidence-based care by focusing on quality measures and removing financial and policy barriers to treatment.

#### **VIII. EXPAND ACCESS TO OVERDOSE-REVERSING DRUGS AND SUPPORT SERVICES, INCLUDING HOUSING AND EMPLOYMENT SERVICES IDENTIFYING AND DISSEMINATING BEST PRACTICES**

Treating overdose victims involves more than just treatment, it involves a comprehensive approach for the best chance to achieve a successful long-term recovery. The Administration has been working with all levels of government to ensure individuals who

experience an overdose have access to life saving drugs and the necessary follow up services. For example, to aid in reemployment services in areas impacted by the opioid crisis, the DoL provided \$22 million in National Health Emergency Dislocated Worker Demonstration Grants to six states in 2017 and 2018.

Timing is critical when dealing with an overdose and having overdose reversing drugs readily available can be the difference between life and death. The Trump Administration has worked on a number of approaches to ensure lifesaving overdose-reversing drugs are easily accessible.

In April 2018, the Surgeon General issued an unprecedented advisory encouraging more individuals, including family, friends, and those who are personally at risk for an opioid overdose to carry naloxone. In December 2018, HHS reinforced this call to action by issuing guidance for healthcare providers and patients detailing how naloxone can help save lives and should be prescribed or co-prescribed to patients at high risk for an opioid overdose.

Currently, all 50 States, the District of Columbia and the Commonwealth of Puerto Rico authorize paramedics to administer the opioid overdose reversing drug, naloxone, but broader access is still needed. In an effort to address this need, in 2017, SAMHSA, provided 12 grants totaling over \$10 million to assist states in purchasing overdose reversing drugs, equipping first responders in high-risk communities, providing training on the use of the drugs and providing materials to assemble overdose kits.

Recognizing the importance of ensuring overdose reversing drugs are properly administered, in 2017, SAMHSA provided \$12 million in grants to 21 organizations under its First Responder Training grant program. In 2018, SAMHSA provided another 28 grants. This program allows first responders and members of other key community sectors to administer an FDA-approved or cleared emergency treatment for a known or suspected overdose. Under this program, the grantees provide training and resources to first responders and others on carrying and administering these products. Grantees also establish protocols for referral to appropriate treatment and recovery communities.

Furthering efforts, BJA awarded almost \$320 million to combat the opioid crisis. The Comprehensive Opioid Abuse Site-based Program accounts for \$162 million of this effort and gives grants to communities across the nation to provide a variety of support services after an overdose. The program also helps fund drug courts, support youth affected by an overdose, and provides treatment options for previously incarcerated members of society.

After an overdose is reversed, it is critical the correct treatment is readily available. The Administration has supported immediate access to effective treatment for overdose survivors. As mentioned above, in 2017, HHS provided more than \$500 million to states for treatment and prevention programs, including programs that fund MAT, prepare individuals with a SUD for treatment, provide behavioral counseling for those in recovery, and expand

treatment opportunities for rural communities. As also mentioned above, in 2018, SAMHSA provided an additional \$1.5 billion to states and tribes for SUD treatment.

Additionally, the Administration has supported efforts to provide the necessary treatment to those involved in the criminal justice system. As part of these efforts, the Administration recently funded 21 new five-year Offender Reentry Program (ORP) grants in 2018. ORP grants help Americans with a SUD who have recently been released from prison by employing “wrap around” services such as housing, job skill training, and childcare coupled with drug testing, SUD treatment, and therapy. The Administration also supports the drug court model, which identifies offenders with severe substance use disorders and provides treatment under judicial supervision, all while reducing recidivism rate and saving money.

**IX. IMPROVE COORDINATION AMONG RESEARCH FUNDING AGENCIES TO IDENTIFY GAPS AND EXPAND RESEARCH RELATED TO FINDING MORE ALTERNATIVES TO OPIOIDS AND TREATMENT FOR ADDICTION, AND GETTING THESE TO PATIENTS FASTER**

President Trump’s *Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand* emphasizes the importance of research and development for innovative technologies and therapies to help treat pain management and prevent addiction. The Administration is addressing this through a collaborative all of government approach focused on research and participation from the private sector.

The National Institutes of Health (NIH), the world’s largest biomedical research agency, has taken the lead on investing in research to address the opioid crisis. In April 2018, NIH launched the HEAL (Helping to End Addiction Long-term) Initiative, an aggressive, inter-agency partnership to get treatments to patients faster. The HEAL Initiative builds on extensive, well-established NIH research, including basic science of the complex neurological pathways involved in pain and addiction, implementation science to develop and test treatment models, and research to integrate behavioral interventions with MAT for OUD. Specifically, the NIH HEAL Initiative directed \$500 million in FY 2018 toward improving treatments for opioid misuse and addiction and enhancing pain management. Through HEAL, NIH funds research to provide new strategies for the prevention and treatment of opioid misuse and addiction to help people with OUD achieve and maintain a meaningful and sustained recovery. The HEAL Initiative focuses efforts on improving pain management by working with partners from the biopharmaceutical industry on data-sharing, new biomarkers for pain, and a clinical trials network for testing new pain therapies.

As part of the HEAL Initiative, NIH is collaborating with FDA and private sector experts to identify areas of opportunity to advance pharmacological treatments for pain and addiction including innovative medications and technologies. Further, in 2018, FDA granted clearance for numerous innovative technologies such as, a new mobile treatment for addiction that offers cognitive behavioral therapy and contingency management, a

percutaneous nerve stimulator for pain, and a wearable neuro-stimulation device for addiction. FDA has also granted approval for longer-acting addiction treatment products and a new product for withdrawal. The National Institute of Drug Abuse, within the NIH, has committed millions of dollars to examine novel approaches to treating OUD, including the use of vaccines to reduce the euphoric effects of opioids and protect against overdose.

Pain research is another area where collaboration is necessary. The NIH Office of Pain Policy and the Interagency Pain Research Coordinating Committee developed the Federal Pain Research Strategy (FPRS) to guide Federal agencies and departments that support pain research and to advance the science to better understand pain and improve care. NIH also supports a broad range of research on pain, targets for the development of non-addictive-therapies and continues to support Centers of Excellence for Pain Education (CoEPEs). The CoEPEs act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to enhance and improve how health care professionals are taught about pain and its treatment.

Integration of prevention and treatment services within the healthcare, community and criminal justice systems is essential to success in combating the opioid crisis. The NIH is studying strategies to improve the implementation of MAT for people with OUD in the criminal justice system. This research aims to optimize implementation of evidence-based screening, assessment, and treatment services by juvenile justice agencies and improve coordination with community healthcare providers in a way that promotes long-term recovery from opioid addiction in real-world settings.

An interagency effort to address this crisis is the Office of Science and Technology Policy Fast-Track Action Committee on Health Science and Technology Response to the Opioid Crisis (Opioid FTAC). Convened under the National Science and Technology Council, subject matter experts from 17 agencies and offices collaborated to develop a report on opportunities for coordination of Federal research and development, including in the areas of pain management, non-biological contributors to opioid addiction, opioid addiction and prevention. The report emphasizes the importance of research on the development of non-addictive alternatives to opioids for treatment of acute and chronic pain.

At times, non-drug approaches to pain management can be a sensible alternative to the use of opioids. HHS, DoD, and the VA have been focusing research projects on nondrug approaches for pain management to address the needs of service members and veterans. A dozen research projects currently underway focus on developing, implementing, and testing cost-effective, large-scale, real-world research on nondrug approaches for pain management and related conditions in military and veteran health care delivery organizations. The Administration's commitment to increase the collaborative work in research and development areas is vital to ensure life-saving treatments and therapies get to patients faster and potentially save lives.

## CONCLUSION

Drug demand and the opioid crisis continues to be the largest public health crisis in a generation. Since taking office, the Trump Administration has met this challenge head-on by engaging in massive action on an unprecedented scale. As part of this engagement, President Trump, for the first time in history, directed all executive agencies to prioritize and use every appropriate authority to fight the opioid crisis. The President's Commission took a comprehensive look at the issue and pursued numerous ideas to address this crisis in its report. Additionally, as part of its interagency response, the Administration secured record funding, had historic success in shutting down illicit suppliers, and signed groundbreaking legislation. While there have been many successes, the Administration recognizes lives are still being lost and there is still an enormous amount of work to do. The Trump Administration is confident that we have begun to turn the tide in this struggle and, with a continued and concerted effort, we will end the opioid crisis.