Trump Administration Response to the Final Recommendations of the President's Commission on Combatting Drug Addiction and the Opioid Crisis

The President's Commission on Combatting 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, and its final report on November 1, 2017. The final report contained 56 recommendations that fell broadly into nine groupings, each representing an overarching goal. In order to facilitate a more accessible public response to the Commission's work, the Administration's response addresses nine overarching goals of the Commission's report.

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

The Administration agrees with the Commission that the opioid crisis requires the Federal Government to direct funding to areas of need with minimal bureaucratic delay and administrative burden. It is also a priority for the Administration to ensure Federal programs and funding for opioid abuse are accountable and effective, using evidence-based approaches. To ensure States have the resources and flexibility they need to quickly respond to the opioid crisis, the Administration has provided States with funding through the Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration's (SAMHSA) State Targeted Response to the Opioid Crisis grants and the Substance Abuse Prevention and Treatment Block Grant. To help ensure that evidence-based practices are used with State Targeted Response funding, a new, national technical assistance program is being developed by SAMHSA to provide State-specific training and assistance to providers for evidence-based practices for opioid use disorder prevention, treatment, and recovery services interventions.

Additionally, Federal discretionary programs provide targeted funding for specific national priorities and can play important roles in driving innovation and encouraging adherence to principles of science and accountability. Done well, these programs support States with a toolbox of evidence-based, effective programs. Discretionary grants include program monitoring and performance reporting mechanisms for high levels of program accountability that help ensure that taxpayer money supports only programs that truly improve and save lives.

The Commission is rightly concerned about complicated and overlapping grant programs with different application and reporting processes. Our current programs evolved over decades, and reforms could make them less burdensome for grantees. Accordingly, the Departments of Health and Human Services (HHS), Justice (DOJ), and Homeland Security (DHS)will vigorously pursue opportunities to streamline reporting and outcome measures for multiple grants that are made to the same state or local grantee.

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

The Administration agrees that we need to enhance awareness and screening to prevent inappropriate use of opioids and other drugs. Raising awareness about the scourge of opioids and other illicit drugs is essential to driving down drug use initiation, which is a critical part of the solution to the crisis. As President Trump has stated, the Administration will launch a prevention-focused media campaign. Additionally, in September 2017, HHS's Centers for Diseases Control and Prevention (CDC) initiated its "Rx Awareness Campaign"—a large, multimedia effort aimed at increasing awareness of prescription opioid risks. The campaign features real-life stories of people recovering from prescription opioid addiction, as well as the stories of those who have lost loved ones to prescription opioid overdose.

Screening tools are particularly valuable for young people in school and college settings, and among patients with pain management needs during their doctor visits. Adolescents who use drugs or alcohol tend to exhibit additional risk factors associated with substance abuse, such as academic difficulties, mental disorders (e.g. depression and anxiety), sexual activity, and fragile family structures. There are many tools available that purport to identify at-risk youth and drive effective interventions, but few show clear evidence of success and many require further research, evaluation, and refinement. To achieve better results at lower costs, it is critical to use evidence-based screening tools, and the Administration, through its funding and technical assistance mechanisms, is supporting states and local stakeholders to adopt these evidence-based interventions.

III. ENHANCE EDUCATION AND TRAINING FOR MEDICAL PROFESSIONALS TO REDUCE INAPPROPRIATE PRESCRIBING PRACTICES

The Administration agrees with the need to enhance education and training for medical professionals, which will help reduce inappropriate prescribing practices. Well-intentioned but ultimately counterproductive pain management efforts have contributed substantially to the opioid crisis. Serious and dramatic efforts must be made to improve the initial education phase for these providers. Perhaps the most important point of intervention is encouraging providers to ask the basic question of whether an opioid is even a necessary treatment for their patient. Provider education, including but not limited to knowledge of alternatives to opioids such as interdisciplinary pain management care, is important to promote safer and more effective pain management for patients.

To address the need for education, agencies across the Federal Government are integrating education and training for providers. For example, CDC has created tools and materials to educate and train providers about applying the CDC Guideline for Prescribing Opioids for Chronic Pain within clinical practice. CDC launched and released a seven-part webinar series through the agency's Clinician Outreach and Communication Activity (COCA) platform and also is developing and releasing an online training series for healthcare providers. And the Pain Management Best Practices Interagency Task Force will be reviewing current pain management best practices and making recommendations to update them and to develop a strategy for disseminating information about such best practices.

Earlier this year, FDA announced its intention to expand Risk Evaluation and Mitigation Strategy (REMS) requirements that already applied to extended-release and long-acting opioid analgesics to also include immediate-release opioid analgesics. This will require manufacturers to provide additional education and training to providers for immediate-release opioid analgesics in addition to the education and training already provided for extended-release and long-acting opioid analgesics. The Opioid Analgesic REMS expansion represents a significant step forward, given that approximately 90% of all opioid analgesic prescriptions are for immediate-release products.

Additionally, this spring, FDA-released draft revisions to its "blueprint" for prescriber education. These revisions will expand the education content by adding the principles of pain management—including non-pharmacologic treatments and non-opioid analgesic medications—as well as how to assess, treat, and monitor patients when opioids are appropriate. The blueprint also has a section on the basics of addiction medicine. Once finalized, the blueprint will provide guidelines for accredited continuing medical education companies to develop prescriber education courses that can be funded through unrestricted educational grants from pharmaceutical companies under the current Extended-Release and Long-Acting Opioid Analgesic REMS. The blueprint would most directly apply to the roughly 1.5 million prescribers registered with the DEA to prescribe controlled substances. Under the blueprint, continuing education would also now be provided for healthcare providers other than prescribers (e.g. nurses and pharmacists) who are involved in the care of patients with pain.

IV. ENHANCE THE USE OF PRESCRIPTION DRUG MONITORING PROGRAMS THROUGH BETTER DATA INTEGRATION AND UTILIZIATION

The Administration strongly agrees with the Commission's endorsement of prescription drug monitoring programs (PDMP) that are nationally interoperable and better integrated into clinical practice. The establishment of and full cooperation with robust and interoperable State PDMPs can help identify and address opioid misuse and abuse. HHS and DOJ provide funding and technical assistance to States to help them develop fully interoperable and integrated PDMP networks within their States.

The Administration has also been rolling out, and will continue to ramp up, aggressive prescription monitoring in government programs to reduce opioid misuse initiation and identify patients at high risk of abuse so that they can be helped before addiction threatens their lives.

V. STRENGTHEN LAW ENFORCEMENT EFFORTS TO TARGET INDIVIDUALS AND ORGANIZATIONS THAT PRODUCE AND SELL COUNTERFEIT OR ILLICIT DRUGS

The Administration agrees with the Commission that fully integrating Federal enforcement activities across all agencies is crucial to long-term success in addressing the opioid crisis. Federal activities to disrupt complex criminal networks supplying illicit opioids to the United States are strengthened when combined with those of State, local, and tribal law enforcement agencies, as well as our law enforcement counterparts in other countries. To better

attack these networks, the United States Government will improve integration and synchronization of intelligence and law enforcement information that is essential to our success. To ensure synchronization of all efforts, the Administration has been implementing its Heroin Availability Reduction Plan (HARP), which is focused specifically on reducing the supply of heroin and synthetic opioids such as illicit fentanyl and its analogues, and developing a national plan against transnational organized crime.

The Administration is working to address the proliferation of illicit fentanyl and fentanyl analogues. This includes ONDCP facilitating interagency coordination efforts to disrupt the sale of illicit drugs over the internet. During the past six months, Federal law enforcement agencies have also taken significant action against illicit fentanyl producers and traffickers. These actions include: taking down the largest criminal marketplace on the internet, Alpha Bay; pursuing indictments, for the first time ever, against Chinese manufacturers of deadly fentanyl and other opioid substances; and the FDA's taking action against online pharmacies that illegally sold potentially dangerous, unapproved versions of prescription medicines, including opioids.

The coordinated efforts of United States law enforcement organizations will build our Nation's cyber capabilities to prevent illicit internet opioid sales, disrupt the illicit fentanyl supply chains, improve law enforcement's ability to identify the origin of illicit shipments and their routing, and ensure the collection, analysis, and utilization of a wide variety of data useful for understanding and responding to the threat posed by opioids.

VI. ENHANCE EFFORTS TO DETECT AND INTERCEPT ILLICIT DRUGS COMING INTO THE COUNTRY

The Administration agrees with the Commission's recommendation that the United States must improve its detection and interdiction capabilities at United States borders and ports of entry. Heroin and illicit fentanyl enter the United States both through traditional drug trafficking methods and through international mail and express consignment. Mexico is the principal conduit of heroin, and a transit country for illicit fentanyl, into the United States due to our shared border. Facilitated by internet-based transactions, powdered fentanyl, however, is directly shipped from Chinese producers to United States consumers, as well as to United States-based distributors. Recognizing the threat posed by illicit opioids, the United States Government has taken steps to better detect and interdict the flow of these dangerous drugs. The United States Government will initiate an aggressive effort to create advanced drug-detection capabilities to improve law enforcement's ability to restrict the flow of these dangerous opioids to our citizens.

ONDCP is working to improve our ability to detect fentanyl in order to further disrupt its supply chain. Customs and Border Protection (CBP) interdicts drugs crossing our land borders, utilizing technology that can detect the illegal transit of drugs hidden on people, in cargo containers, and in other conveyances. In furtherance of these efforts, CBP has initiated a rapidly expanding pilot program to enable the detection of fentanyl compounds by canine teams.

CBP also uses Advanced Electronic Data (AED) collected by the United States Postal Service (USPS) to identify incoming shipments for advance targeting based upon intelligence, prior violations, and other risk factors. USPS currently receives AED on nearly half of all

inbound packages from international sources. Recently, China agreed to provide AED, which will dramatically enhance CBP's detection abilities. USPS and CBP are aggressively encouraging additional countries of origin to supply AED.

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 agrees with the goal to revise and enhance reimbursement policies to support addiction treatment and its co-morbid mental health and physical conditions. The Centers for Medicare & Medicaid Services (CMS) announced a bold new policy that increases the flexibility for States to apply for new expenditure authority to address one of the biggest barriers to treatment: the decades-old statute that prohibits Medicaid—the healthcare safety net program for the poor—from paying for inpatient or residential addiction treatment at facilities with more than 16 treatment slots. Under CMS' new policy, States can more quickly gain approval for new expenditure authority to help patients in certain inpatient or residential treatment facilities while the State is building their broader treatment capacity. Two States have already received approvals under the new policy (New Jersey and Utah) and several more applications have come in for review.

The Department of Labor (DOL) will expand access to treatment and recovery services by continuing to educate private payers regarding the requirements of the Mental Health Parity and Addiction Equity Act and vigorously enforcing the law. For fiscal year 2018, the DOL's Employee Benefits Security Administration has committed to issuing additional guidance addressing impermissible treatment limitations on mental health and substance use disorder benefits.

SAMHSA, in 2017, conducted two Parity Policy Academies for 30 States, providing them with technical assistance for improved parity implementation in the commercial insurance market, the Medicaid program, and the Children's Health Insurance Program (CHIP). SAMHSA continues to engage with stakeholders to advance these efforts.

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

The Administration strongly supports the Commission's goal of expanding access to overdose-reversing drugs and recovery support services, including housing and employment services, and it is currently working to identify and disseminate best practices. There are, for example, many ways to expand access to naloxone, a lifesaving medication that can reverse opioid overdose. Some of these, like adopting standing orders issued by prescribers or public health authorities, liability protections for prescribers, and "Good Samaritan" laws, have already been widely adopted in many States.

The Administration is continuing to work to identify additional best practices and to disseminate such promising approaches to States and other stakeholders. For example, the period immediately following overdose reversal with naloxone can provide a unique window of opportunity to engage survivors, to link them directly to substance abuse treatment and peer recovery support services, and to equip them and their family members with naloxone and train them in its administration in the event of a future overdose. In an increasing number of hospital emergency departments, this work is being done by peer recovery coaches who engage patients, offer a warm handoff to treatment, and remain engaged with patients for 90 days or more following their discharge from the emergency department. When deployed through a recovery community organization, these peer recovery coaches can also link individuals directly to supportive social networks of people in recovery and to services, such as assistance in securing open-market housing, recovery housing, and employment. In addition, medically managed opioid withdrawal through hospitals or detoxification units offers a unique opportunity not only to provide overdose prevention training and to distribute naloxone, but also to initiate medication for treatment of opioid addiction that can be continued in outpatient settings. This saves lives, since people are at an especially high risk for overdose after detoxification if they do not continue in treatment.

In September 2017, SAMHSA provided funding to organizations under its First Responder Training grant program to train and provide resources to first responders and members of other key community sectors at the State, Tribal, and local governmental levels on carrying and administering overdose-reversing drugs. In addition, SAMHSA provided grant funding under its Prevent Prescription Drug/Opioid Overdose-Related Deaths grant program to assist States in purchasing overdose reversing drugs, equipping first responders in high-risk communities, providing training on the use of these drugs, and providing materials to assemble and disseminate overdose kits.

IX. IMPROVE COORDINATION AMONG RESEARCH-FUNDING AGENCIES TO IDENTIFY GAPS AND EXPAND RESEARCH RELATED TO FINDING AND EXPANDING ACCESS TO PAIN MANAGEMENT ALTERNATIVES TO OPIOIDS AND TO DISCOVER ADDITIONAL TREATMENTS FOR ADDICTION

The Administration agrees that additional research and coordination are important for reducing reliance on addictive medicines for pain management; reducing overdoses from these medicines; decreasing the exposure of people susceptible to addiction to prescription opioids, illicit fentanyl, and heroin; and expanding options for treating addiction. It is important also to promote and improve treatment strategies for non-pharmacological approaches to pain management.

The National Institutes of Health (NIH) has begun developing a partnership with innovator companies to help facilitate the development of new treatments for pain, addiction, overdose-reversal, and non-addictive therapies for pain. This public-private initiative will advance research to address the opioid crisis. It is important to include regulators and payers in these efforts, as the research community too often works in silos, which insulates them and can

delay new therapies and cures from coming to market and to patients. NIH is considering plans to engage CMS to address reimbursement challenges for medications, as well as medical devices that may disincentive industry from investing in this area.

To address coordination needs, the White House Office of Science and Technology Policy will convene an interagency body to coordinate opioid-related health Research and Development (R&D) investments in science and technology across the Administration. Through this effort, the Administration will increase collaboration across agencies and with the private sector to develop an opioid R&D strategy to combat the public health threats of the crisis.