

Dear Mr. President:

I am proud to present to you today the interim report prepared by your Commission on Combating Drug Addiction and the Opioid Crisis. This interim report is just a start; our work is ongoing and we will have more to share with you and the nation later in the Fall of 2017. We now recommend several actions for you to take as our nation's Chief Executive and someone who spoke passionately on this issue in the 2016 campaign.

Our nation is in a crisis. Your Executive Order recognized that fact. The work of your Commission so far acknowledges the severity of this national problem.

According to the Centers for Disease Control (CDC), the most recent data estimates that 142 Americans die every day from a drug overdose. Our citizens are dying. We must act boldly to stop it. The opioid epidemic we are facing is unparalleled. The average American would likely be shocked to know that drug overdoses now kill more people than gun homicides and car crashes combined. In fact, between 1999 and 2015, more than 560,000 people in this country died due to drug overdoses – this is a death toll larger than the entire population of Atlanta. As we have all seen, opioids are a prime contributor to our addiction and overdose crisis. In 2015, nearly two-thirds of drug overdoses were linked to opioids like Percocet, OxyContin, heroin, and fentanyl. This is an epidemic that all Americans face because here is the grim reality: Americans consume more opioids than any other country in the world. In fact, in 2015, the amount of opioids prescribed in the U.S. was enough for every American to be medicated around the clock for three weeks.

Since 1999, the number of opioid overdoses in America have quadrupled according to the CDC. Not coincidentally, in that same period, the amount of prescription opioids in America have quadrupled as well. This massive increase in prescribing has occurred despite the fact that there has not been an overall change in the amount of pain Americans have reported in that time period. We have an enormous problem that is often not beginning on street corners; it is starting in doctor's offices and hospitals in every state in our nation.

But, the challenge of reducing opioid supplies has evolved. As access to prescription opioids tightens, consumers increasingly are turning to dangerous street opioids, heroin, fentanyl alone or combined, and mingled with cocaine or other drugs. In 2016, specific states witnessed an escalating number of overdose deaths due to heroin and/or fentanyl(s), in some states vastly exceeding deaths due to prescription opioids.

In 2015, 27 million people reported current use of illegal drugs or abuse of prescription drugs. Despite this self-reporting, only 10 percent of the nearly 21 million citizens with a substance use disorder (SUD) receive any type of specialty treatment according to the most recent National Survey on Drug Use and Health. This is contributing greatly to the increase of deaths from overdose.

Over forty percent of people with a substance use disorder also have a mental health problem, but less than half of these people receive treatment for either issue. The reasons for these

treatment gaps are many, including lack of access to care, fear of shame and discrimination, and lack of motivation to seek treatment.

This Commission has been hard at work to meet the goals set for us in the Executive Order on March 29th, 2017. As a Commission, we have already met with leading national organizations in the addiction space, and we have received information and recommendations from countless individuals and groups, all of whom share in our commitment to beating this epidemic. The Commission thanks all the individuals and organizations, including Governors and representatives from Governors Offices from around the country, that have reached out to offer their experiences, expertise, and input.

In addition to conducting phone calls with Governors and their teams in all 50 states, we also held a listening session with bi-partisan members of Congress, and key cabinet members of your Administration. Individual Commission members have organized “listening sessions” and solicited recommendations from treatment providers, addiction psychiatrists and other physicians, data analysts, professional medical and treatment societies, medical educators, healthcare organizations, pharmacoepidemiologists, and insurance providers. Outreach also has been made to scientists with broad expertise in pain, addiction biology and treatment.

The first public meeting of the Commission was held on June 16th at the White House, and was a great success. The Commission members heard comprehensive public testimony by nine leading nonprofits, and have received more than 8,000 comments from the public, including comments from at least 50 organizations.

This information was reviewed by the Commission members and helped inform this interim report.

The first and most urgent recommendation of this Commission is direct and completely within your control. Declare a national emergency under either the Public Health Service Act or the Stafford Act. With approximately 142 Americans dying every day, America is enduring a death toll equal to September 11th every three weeks. After September 11th, our President and our nation banded together to use every tool at our disposal to prevent any further American deaths. Your declaration would empower your cabinet to take bold steps and would force Congress to focus on funding and empowering the Executive Branch even further to deal with this loss of life. It would also awaken every American to this simple fact: if this scourge has not found you or your family yet, without bold action by everyone, it soon will. You, Mr. President, are the only person who can bring this type of intensity to the emergency and we believe you have the will to do so and to do so immediately.

The Commission is additionally proposing the following recommendations for action:

- **Rapidly increase treatment capacity. Grant waiver approvals for all 50 states to quickly eliminate barriers to treatment resulting from the federal Institutes for Mental Diseases**

(IMD) exclusion within the Medicaid program. This will immediately open treatment to thousands of Americans in existing facilities in all 50 states.

The Commission has been urged by every Governor, numerous treatment providers, parents, and non-profit advocacy organizations to eliminate the IMD exclusion within the Medicaid program. This component of the Social Security Act prohibits federal Medicaid funds from reimbursing services provided in an inpatient facility treating “mental diseases” (including SUDs) that have more than 16 beds. This exclusion makes states entirely responsible for Medicaid-eligible patients in inpatient treatment facilities, including patients undergoing withdrawal management in addiction treatment facilities rather than hospitals. The Commission members that serve as Governors, as well as individuals and organizations that treat Medicaid patients, are intimately aware of how the IMD exclusion impacts the ability to serve patients with severe SUDs that are best served in an inpatient setting. The Commission recognizes that legislation would be necessary to repeal the exclusion in its entirety. However, certainly after an emergency declaration by the President (and arguably even without it) the Department of Health and Human Services (HHS) Secretary would be empowered to immediately grant waivers to each state that requests one. This is the single fastest way to increase treatment availability across the nation.

- **Mandate prescriber education initiatives with the assistance of medical and dental schools across the country to enhance prevention efforts. Mandate medical education training in opioid prescribing and risks of developing an SUD by amending the Controlled Substance Act to require all Drug Enforcement Administration (DEA) registrants to take a course in proper treatment of pain. HHS should work with partners to ensure additional training opportunities, including continuing education courses for professionals.**

According to a Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Behavioral Health and Statistics Quality (CBHSQ) report, four out of every five new heroin users begin with nonmedical use of prescription opioids.

In other words, Mr. President, this crisis began in our nation’s health care system. While we acknowledge that some of this inappropriate overprescribing is done illegally and for profit, we believe the overwhelming percentage is due to a lack of education on these issues in our nation’s medical and dental schools and a dearth of continuing medical education for practicing clinicians. This can and must be solved by using Presidential moral and legal authority to change this lack of education leading to addiction and death.

There are several initiatives around the country aimed at ensuring that providers are aware of the potential for misuse and abuse of prescription opioids.

Governor Baker’s administration in Massachusetts has worked with the medical and dental schools in that state and the Medical Society to develop core competencies related to opioids and SUDs that all graduating students are expected to learn and put into practice. Other states such as Arizona, Connecticut, Pennsylvania, New York, and Utah have expanded continuing medical education requirements for opioid prescribers and

dispensers. Alternatively, the American Society of Addiction Medicine (ASAM) has recommended implementing a requirement that clinicians who apply for a registration with the DEA to prescribe controlled substances demonstrate competency in safe prescribing, pain management, and substance use identification. In New Jersey, Governor Christie recently signed a law that requires providers themselves to take continuing education related to opioids, and requires prescribers to discuss the risks of opioid dependence with their patients prior to the first prescription. We urge national implementation of these initiatives.

In our first Commission meeting, we heard from several nonprofits about the need to promote expanded implementation of the CDC *Guideline for Prescribing Opioids for Chronic Pain* through increased prescriber education initiatives. The Office of National Drug Control Policy (ONDCP) estimates that, apart from federal prescribers who are required to be trained, fewer than 20% of the over one million prescribers licensed to prescribe controlled substances to patients have training on how to prescribe opioids safely. Similarly, it seems that many medical providers are not well-versed on how to screen for addiction, and what to do if a patient has become dependent on substances or presents with an SUD. We urge you to instruct the Department of Justice (DOJ) and the DEA to require continuing medical education for every physician requesting an initial DEA license or the renewal of such a license.

The CDC and the U.S. Food and Drug Administration (FDA) should finalize, review and recommend national training standards working with the Accreditation Council for Continuing Medical Education (ACCME) to ensure training courses are coordinated with other federal agencies, professional societies, medical schools, and residency programs to avoid discrepancies.

The FDA should also work with the ACCME to develop data analytics to determine whether courses change practices, increase patient referrals to treatment, and methods to improve compliance consistent with opioid prescribing education.

Clinicians need more detailed and specific guidance on drug choice, dose, and quantity to be dispensed in treating specific pain conditions. We also recommend a detailed analysis of, and solutions to clinical problems encountered in applying recommended guidelines.

- **Immediately establish and fund a federal incentive to enhance access to Medication-Assisted Treatment (MAT). Require that all modes of MAT are offered at every licensed MAT facility and that those decisions are based on what is best for the patient. Partner with the National Institutes of Health (NIH) and the industry to facilitate testing and development of new MAT treatments.**

MAT has proven to reduce overdose deaths, retain persons in treatment, decrease use of heroin, reduce relapse, and prevent spread of infectious disease. Expansion of MAT availability for qualified individuals and for short- or long-term treatment is an essential

component of treatment services. Yet approximately 10 percent of conventional drug treatment facilities in the United States provide MAT for opioid use disorder.

Individuals seeking SUD treatment, and even those currently enrolled in a treatment system, often find barriers to using MAT as a component of their treatment. Particularly for populations with opioid use disorders (OUDs) involved in the criminal justice system, there is often inadequate access to FDA-approved medications that are proven to improve outcomes as part of a full continuum of care. Multiple studies have shown that individuals receiving MAT during and after incarceration have lower mortality risk, remain in treatment longer, have fewer positive drug screens, and have lower rates of recidivism than other individuals with OUDs that do not receive MAT. The DOJ, in consultation with HHS and ONDCP, should be directed to increase the use of MAT for OUDs in these correctional settings.

In addition, the Centers for Medicare & Medicaid Services (CMS) should require all federally-qualified health centers (FQHCs) to mandate that their staff physicians, physician assistants, and nurse practitioners possess waivers to prescribe buprenorphine.

There are several barriers to the use of MAT, including a prevalent belief that use of MAT does not constitute true recovery or sobriety. The Federal Government, as a major purchaser of health care services, has a tremendous opportunity to increase the availability of MAT for individuals with OUDs. For example, across the Veterans Administration (VA) and Indian Health Services, there is a lack of providers able to prescribe/administer MAT. For Medicare patients, the Part B physician benefit does not cover methadone treatment and the Part D pharmaceutical benefit does not cover it either, as it is administered by a medical professional. CMS should send a letter to state health officials requesting that state Medicaid programs cover all FDA-approved MAT drugs for OUD.

Additionally, all FDA-approved MAT should be offered by authorized providers, not just one or two of these approved options. These decisions of which (if any) MAT to be used must be based upon what is best for the patient, not what is best for the provider. This can be mandated by the Executive Branch.

Finally, we urge you to instruct the NIH to begin to immediately work with the pharmaceutical industry in two areas; the development of additional MAT options and the development of new, non-opioid pain relievers based on research to clarify the biology of pain. The nation needs more options to treat those already addicted and can help to prevent addiction in the first place by avoiding the prescription of opioids. The NIH is best positioned, in our opinion, to lead this effort with industry partners.

- **Provide model legislation for states to allow naloxone dispensing via standing orders, as well as requiring the prescribing of naloxone with high-risk opioid prescriptions; we must equip all law enforcement in the United States with naloxone to save lives.**

Naloxone is a lifesaver that rapidly reverses opioid overdose. It is the first line of defense in many parts of our country; if we lose someone to overdose we obviously have no chance to

treat them and return them to a productive life. We urge you to mandate, with federal assistance, that naloxone be in the hands of every law enforcement officer in the United States. By declaring a national emergency, you can empower the HHS Secretary to negotiate reduced pricing for all governmental units. Forty-seven states have expanded access to naloxone in some form. The Federal Government should ensure that naloxone is made available when there is the greatest chance for an overdose. Accordingly, model legislation should include a requirement that naloxone is prescribed in combination with any CDC-defined high-risk opioid being prescribed.

An impediment to naloxone usage and people seeking help in the event of an overdose is the perceived threat of law enforcement involvement. Overly restrictive or punitive laws may prevent the uptake of naloxone or the seeking of aid in an emergency. In response, most state legislatures and some law enforcement agencies have created a variety of immunity and ‘Good Samaritan’ laws to ensure bystanders and those experiencing an overdose are not deterred from seeking immediate help. States vary widely in the content of ‘Good Samaritan’ laws, but they generally offer protection to people assisting at the scene of an overdose, or seeking care for their own or another’s overdose, from civil or criminal prosecution. As of July 2017, 40 states and the District of Columbia have enacted some form of a ‘Good Samaritan’ or 911 drug immunity law. In addition to enacting legislation, it is crucial that states ensure the public fully understands the protections provided by the ‘Good Samaritan’ law and how it empowers them to call 911 in the case of an overdose.

HHS and other federal agencies should be directed by you or your cabinet to make recommendations on ways to identify persons who have overdosed and been revived with naloxone and the feasibility of notification of their primary care and other physicians caring for them. These primary care providers may be prescribing medications that increase future risks of another overdose.

- **Prioritize funding and manpower to the Department of Homeland Security’s (DHS) Customs and Border Protection, the DOJ Federal Bureau of Investigation (FBI), and the DEA to quickly develop fentanyl detection sensors and disseminate them to federal, state, local, and tribal law enforcement agencies. Support federal legislation to staunch the flow of deadly synthetic opioids through the U.S. Postal Service (USPS).**

Illicit fentanyl and fentanyl analogs are the next grave challenge on the opioid front and the awful news is that it is much, much more deadly than hydrocodone, oxycodone or even heroin. Since 2012, the nation has seen an alarming increase in the number of drug overdose deaths that involve fentanyl, a synthetic opioid many times more powerful than heroin, as well as heroin and cocaine laced with non-pharmaceutical fentanyl. Fentanyl defies detection at our borders, as the small quantities involved for psychoactivity of fentanyl and fentanyl analogs challenge Customs and Border Protection, USPS, and express consignment carriers’ ability to detect and interdict. We are miserably losing this fight to prevent fentanyl from entering our country and killing our citizens. We are losing this fight predominately through China. This must become a top tier diplomatic issue with the

Chinese; American lives are at stake and it threatens our national security. Our inability to reliably detect fentanyl at our land borders and at our international mail handling facilities creates untenable vulnerabilities. Key federal agencies, including the DEA, DHS, FBI, and DOJ, should coordinate pursuant to the Controlled Substances Act to intercept fentanyl (and other synthetic opioids) in envelopes and packages at mail processing distribution centers, and increase detection efforts using enhanced technology, more manpower, and expanded canine deployment. Only a presidential directive will give this issue the top level attention it deserves from DOJ, DHS, and USPS.

- **Provide federal funding and technical support to states to enhance interstate data sharing among state-based prescription drug monitoring programs (PDMPs) to better track patient-specific prescription data and support regional law enforcement in cases of controlled substance diversion. Ensure federal health care systems, including Veteran's Hospitals, participate in state-based data sharing.**

PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs. They are designed to give providers access to critical information regarding a patient's controlled substance prescription history, and can help health professionals identify patients who may be or are at risk of misusing prescription opioids or other prescription drugs. PDMPs are also used by professional licensing boards to identify clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion. Multiple published best practices for utilizing PDMPs, including guidelines from the Heller School for Social Policy and Management at Brandeis University, have identified interstate data sharing among PDMPs as a top priority to ensure that healthcare professionals and law enforcement have a complete picture of prescribing practices and controlled substances diversion. Numerous professional health organizations, including the American Medical Association (AMA) and the Association of State and Territorial Health Officials (ASTHO), agree that PDMPs are an effective and important clinical tool to combat the addiction crisis; however, they are being significantly underutilized in the vast majority of our states. Forty-nine states now have PDMPs but not nearly a majority of those are sharing their information. This is unacceptable. We urge you to direct the VA and HHS to lead an effort to have all state and federal PDMP systems to share information and to set a deadline of July 1, 2018 to achieve this data sharing.

In addition to sharing data between states and the federal government, the PDMP needs to be improved with regard to its ease of use, and inclusion of other data to assist prescribing doctors. Ideally, clinicians should check their state PDMP before making the decision to prescribe either an opioid or benzodiazepine (several states already have this requirement in place), determine whether their patient has had an overdose, and other relevant information that can be summarized into categories of high to low risk.

- **Better align, through regulation, patient privacy laws specific to addiction with the Health Insurance Portability and Accountability Act (HIPAA) to ensure that information about SUDs be made available to medical professionals treating and prescribing medication to a**

patient. This could be done through the bipartisan Overdose Prevention and Patient Safety Act/Jessie's Law.

Providers and other advocates have found that certain privacy regulations, while well-intentioned patient protections, act as a barrier to communication between providers, can make it difficult for family members to be involved in a loved one's treatment, and limits the ability to use electronic health records to their full potential. 42 CFR Part 2, which requires addiction treatment professionals to acquire written patient consent before sharing any information with a patient's other health care providers, including when the addiction treatment facility is part of a larger health care system, is a particular hindrance to comprehensive health care. Making it administratively difficult for providers to share information has ill-effects on patients in both physical and behavioral health settings, by restraining physicians' ability to make informed healthcare decisions.

We urge you to direct that regulation be changed to permit the sharing of this type of information among health care providers and the loved ones of those suffering from SUDs. Otherwise, drugs with high abuse liability may be prescribed to people with OUD. That will lead to even more unnecessary and preventable deaths.

- **Enforce the Mental Health Parity and Addiction Equity Act (MHPAEA) with a standardized parity compliance tool to ensure health plans cannot impose less favorable benefits for mental health and substance use diagnoses versus physical health diagnoses.**

As Congressman Kennedy spoke eloquently about at the first Commission meeting, there has long been a difference in how individuals with health insurance receive treatment and medication for physical health diagnoses versus mental health and SUD diagnoses. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) prohibits health insurance plans that cover behavioral health from imposing benefit limitations on mental health or SUD treatment that are less favorable than limitations imposed on medical or surgical benefits. Benefit limitations can be quantitative, such as visit limits, or non-quantitative, such as pre-authorization requirements. But not providing real parity is already illegal. The Commission urges you to direct the Secretary of Labor to enforce this law aggressively and to penalize the violators.

The Commission heard from numerous organizations, including ASAM and the American Academy of Addiction Psychiatry, about the need to systematically monitor and enforce MHPAEA with a standardized tool, and actual penalties for non-compliance, to ensure parity in the coverage of mental health and addiction treatment services. The Labor Secretary, with appropriate direction from you, is the person to do this.

At this point, the largest outstanding issue is treatment limits. Patients seeking addiction treatment, including MAT, are often subjected to dangerous fail-first protocols, a limited provider network, frequent prior authorization requirements, and claim denials without a transparent process. The Commission applauds SAMHSA's work with multidisciplinary teams from states to improve parity enforcement and public education. However, we need

robust enforcement of the parity law by the state and federal agencies responsible for implementing the law. Regulators should be required to levy penalties against health plans that violate MHPAEA, and information about parity violations should be made available to the public.

It is not only critical that the Federal Government provide sufficient resources to prevent and combat this disease; it must also provide the easiest pathway for private providers and local and state governments to achieve success.

That is why the Commission, as a primary focus of the final report, is undertaking a full-scale review of federal programs, regulations, laws, and funding mechanisms targeted toward addressing addiction.

In addition to a full review of federal funding and programs and obstacles and opportunities for treatment, the final report will include, but not be limited to, a more thorough examination of the following issues:

- Development of a national prevention strategy using “big data analytics” to devise targeted prevention messages that employ cutting-edge methods of marketing and communications.
- Evidence-based prevention programs for schools, and tools for teachers and parents to enhance youth knowledge of the dangers of drug use, as well as early intervention strategies for children with environmental and individual risk factors (trauma, foster care, adverse childhood experiences (ACEs), and developmental disorders).
- The need for satisfaction with pain level as a satisfaction criteria through which health care providers are evaluated by HHS.
- Workforce access and training needs within the treatment community nationally, with a particular focus on the regions of the country with the highest overdose deaths.
- Improvements in treatment programs, based on adherence to principles of evidence-based treatment, continuum of care, outcome measures, and patient education on quality treatment.
- Research initiatives and opportunities to combat the epidemic and enhance treatment options, including alternative pain management strategies, and treatment for vulnerable populations such as pregnant women, and substance-exposed infants through work by the NIH, HHS, CDC, FDA, SAMHSA, and pharmaceutical partners.
- Opportunities to further the practice of substance use screenings and referrals through CMS quality measures.
- Opportunities for patient protections providing better information about the risks and benefits of taking prescription opioids.
- Supply reduction of heroin, fentanyl analogs and counterfeit pills through coordinated federal and state law enforcement initiatives.
- Targeted data collection and analytics needed to identify most effective prevention and treatment strategies, quality treatment access programs, reimbursements, and aid to law enforcement activities. The possibility of a behavioral health surveillance system run

through CDC that tracks prevalence rates, treatment modalities, and comorbidities with other illnesses in real-time.

- Regulatory or statutory changes to reduce commercial insurance barriers to MAT, such as dangerous fail-first protocols and onerous and frequent prior authorization requirements.

In our final report, we will provide an additional set of detailed recommendations that, if implemented, will ensure that the Federal Government operates as a strong partner in the fight against addiction and the opioid crisis.

Finally, our country needs you, Mr. President. We know you care deeply about this issue. We also know that you will use the authority of your office to deal with our nation's problems. The Commission looks forward to submitting its final report.

Sincerely,

Commission members