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December 5, 2018

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Senior Policy Advisor, Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

RE: Health Research and Development to Stem the Opioid Crisis: A National Roadmap

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Dear Ms. Brenner,

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On behalf of the American Psychiatric Association (APA), the national medical specialty society representing more than 37,800 psychiatric physicians nationwide, we are writing in response to the Administration's draft report, "Health Research and Development to Stem the Opioid Crisis: A Federal Roadmap," as published in the Federal Register on November 5, 2018. As the providers on the frontlines of this crisis, we are committed to working with the Administration and the states to achieve advancements to turn the tide on this crisis. We appreciate the opportunity to provide feedback on this important research effort.

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Pain Management and Prevention of Opioid Addiction

We are encouraged to see the draft report includes a focus on research to better assess pain in patients and interventions to reduce the misuse of opioids. As we address this crisis, we recognize that a balance must be struck in assessing the risks of opioids, while also maintaining access for patients with acute or terminal pain benefit from these drugs. Our concern is always patient safety, but we want to ensure that interventions do not interfere with the physician-patient relationship and a doctor's ability to help manage his or her patients' needs. **Any proposed interventions to reduce opioid misuse should not impose burdensome requirements on prescribers, such as prior authorizations and additional paperwork, which lead to less time with patients. Additionally, we encourage the Administration to study pharmacy-based interventions, as any proposed intervention should not enable pharmacies to dictate how providers prescribe treatment, nor keep patients from getting their prescriptions filled.**¹

Administration

Saul Levin, M.D., M.P.A.
CEO and Medical Director

We support the Administration's efforts to identify strategies to improve the interoperability of Prescription Drug Monitoring Programs (PDMP) across state lines, but we would like to underscore that any effort should build upon the existing state-built PDMPs. Forty-nine states and the District of Columbia

¹ "Position Statement on Legislative Attempts Permitting Pharmacists to Alter Prescriptions." American Psychiatric Association. 2017.

currently operate PDMPs² tailored to their specific state needs, and we encourage collaboration with state leaders to leverage the local infrastructure for better communications across state lines. One concern we have about the current reporting standards in PDMPs is that not all dispensed medications, such as methadone, have to be reported. If a provider does not realize that such information is not included, and the provider does not obtain a full history from the patient, the provider may inadvertently prescribe medication that could interact with the medication not reported in the PDMP and harm the patient. As the Administration focuses its research in this area, **we recommend that all PDMPs include a notice to providers that clearly states the drugs excluded from the program so providers can better understand the limitations of the reported information.**

Treatment of Opioid Addiction and Withdrawal

We are pleased to see the Administration's draft report prioritize research in treatment for opioid use disorder (OUD), and specifically highlight efforts to define best practices for treating pregnant and breast-feeding women with OUD. This vulnerable patient population needs comprehensive care for both immediate and long-term symptoms, in order to restore a healthy maternal-infant relationship and improved functioning in the mother. The initiation or continuation of Medication Assisted Treatment (MAT) is essential and should be provided for pregnant and breast-feeding women with OUD. Further, we strongly recommend that substance use disorder treatment programs maintain, affiliate, or develop special program initiatives for pregnant, breastfeeding, and newly-delivered women that provide effective, culturally congruent, and collaborative care to assist the mother-infant dyad especially in the critical developmental period of the first 12 months following delivery.

We also support the Administration's focus on conducting research to inform the development of clinical best practices, and we encourage you to examine the barriers providers face in delivering OUD treatment. As an active partner in SAMHSA's Providers' Clinical Support System, a program that has trained over 130,000 providers on the most effective MAT, we know there have been bold efforts to greatly improve the number of trained providers (including physician assistants and nurse practitioners). However, many providers are not prescribing to their maximum capacity: 275 patients per physicians and 100 patients per physician assistants and nurse practitioners. In fact, a 2015 study reported that 48.1% of waived physicians were prescribing buprenorphine to five patients or fewer.³ Another study estimated that roughly half of individuals with OUD would be treated if all opioid treatment providers were prescribing to their permitted capacity.⁴ We encourage the Administration to assess this disconnect among providers.

As the Administration looks to innovative strategies to enhance access to care, we also urge you to study how the Collaborative Care Model (CoCM) can be implemented to treat OUD in primary care settings. We applaud the National Institute of Health's announcement to study the model to meet the needs of individuals with OUD as part of its Helping to End Addiction Long-term (HEAL) Initiative. Three decades of research and over 80 randomized controlled trials have identified the CoCM as delivering high quality

² Vestal, Christine. "[In Opioid Epidemic, States Intensify Prescription Drug Monitoring.](#)" December 2017.

³ Sigmon SC. The Untapped Potential of Office-Based Buprenorphine Treatment. *JAMA Psychiatry*. 2015; 72(4): 395–396. doi:10.1001/jamapsychiatry.2014.2421

⁴ Jones, C. M., Campopiano, M., Baldwin, G., & McCance-Katz, E. (2015). National and state treatment need and capacity for opioid agonist medication-assisted treatment. *American Journal of Public Health*. 105(8).

care coordination of mental health and substance use disorders in and primary care, which is proven to reduce costs, improve access to mental health and substance use services and improve provider satisfaction. This model was recognized by CMS as a validated model and recently created new CPT codes for payment of this model of care. A CoCM team is led by a primary care provider and includes a behavioral health care manager and a consulting psychiatrist. The team implements a measurement-guided care plan and focuses attention on patients not meeting their clinical goals. The psychiatric consultant will review each patient's progress and make treatment recommendations as needed. The ability to leverage the psychiatric consultant by one or more PCPs allows more patients to be covered by one psychiatrist. The evidence base for treating substance use disorders indicates that regular follow-up, medication-assisted treatment, psychosocial interventions, promotion of medication adherence, and case management are important features for successful treatment.

Overdose Prevention and Recovery

Among the most promising areas of research outlined in the Administration's draft report is a focus on determining how to prevent overdose and best support recovery. We support the report's focus on developing novel vaccines, devices and medication to prevent opioid overdoses, as well as tools to detect patient use of novel synthetic opioids. The report also outlines research on access to and the delivery of overdose reversal products. There is mounting evidence that naloxone can save lives and it is a critical public health tool that should be widely available to communities around the country. To better coordinate its distribution and effectiveness to save lives, we encourage you to study the general public's understanding of the medication and the impact of standing pharmacy orders, which would allow all individuals to obtain this medication without a prescription. Additionally, as you work to identify trends in fatal and non-fatal overdoses, we urge you to consider that patients are particularly vulnerable following an overdose and transitioning from care, for example, from the emergency room, jail,⁵ or rehabilitation⁶. We recommend the research include a focus on best practices for warm handoffs to connect patients with a heightened risk of overdose to the community resources they need.

We also encourage the Administration to study recovery methods that include treatment for co-occurring mental and/or physical conditions. As noted in the draft report, many individuals with addiction and/or mental disorders have experienced a significant level of trauma and/or Adverse Childhood Experiences (ACE) (an ACE can be defined as exposure to emotional, physical, or sexual abuse and other adverse conditions, such as poverty). Research highlights that experiencing ACEs is not only associated with an increased risk of substance use and/or other mental health disorders, but also with poor health outcomes in adulthood.⁷ It is critical that patients be treated wholly to improve recovery outcomes, and we reiterate the importance of this area of research.

⁵ Sarah E. Wakeman BA, Sarah E. Bowman BA, Michelle McKenzie MPH, Alexandra Jeronimo BA & Josiah D. Rich MD, MPH(2009). "Preventing Death Among the Recently Incarcerated: An Argument for Naloxone Prescription Before Release." *Journal of Addictive Diseases*, 28:2, 124-129.

⁶ Wines JD, Saitz R, Horton NJ, Lloyd-Travaglini C, Samet JH. "Overdose after detoxification: a prospective study." *Drug Alcohol Depend*. 2007; 89:161-9.

⁷ Monnat SM, Chandler RF. "Long-term physical health consequences of adverse childhood experiences." *Sociologically Quarterly*. 2015; 56(4): 723-752.

Additional Research Opportunities

We are pleased to see the roadmap's additional focus on the biology and chemistry of pain and opioid addiction, the non-biological contributors to opioid addiction, community impact, and opportunities for enhanced coordination. We know that addiction is a complex brain disease and seeking treatment can take several attempts. We applaud the Administration's efforts to contextualize both the science and the social determinants of health that impact a patient's recovery outlook. Additionally, it is important to address the issue of stigma that still surrounds substance use disorders, and this research could move the needle on this issue. **Lastly, we encourage the Administration to use the term "opioid use disorder" over "opioid addiction" to be consistent with the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).**⁸

The APA stands at the ready to join the Administration in your work to combat this public health crisis, and we thank you for your ongoing efforts. If you have questions, or if we can be of further assistance, please contact Michelle Dirst, Director of Practice Management & Delivery Systems Policy, at mdirst@psych.org.

Best,

A handwritten signature in black ink that reads "Saul Levin, MD, MPA". The signature is written in a cursive, flowing style.

Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director

⁸ American Psychiatric Association. *Diagnostic and Statistic Manual of Mental Disorders*. 5th edition, 2013.