May 31, 2016

The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: Jinhee Lee
5600 Fishers Lane, Room 13E21C
Rockville, Maryland 20857

Medication Assisted Treatment for Opioid Disorders, RIN 0930-AA22

Dear Dr. Lee:

On behalf of Trust for America's Health (TFAH), a nonprofit, nonpartisan public health advocacy organization dedicated to making disease prevention and health promotion national priorities, I am pleased to submit the following comments regarding the Medication Assisted Treatment for Opioid Disorders Proposed Rule.[1]

The opioid epidemic in the United States has grown to an alarming degree and constitutes a major public health crisis. In 2014, there were 47,055 lethal drug overdoses, making drug overdose the leading cause of accidental death in the U.S.[2] Prescription pain relievers were involved in 18,893 of these overdose deaths, and heroin was involved in 10,574. From 2008 to 2013, deaths involving heroin more than doubled.[3] Given that only 10 percent of the 23 million Americans with substance use disorder are estimated to be getting treatment,[4] a comprehensive approach to addiction that ensures accessible treatment is essential.

TFAH therefore strongly supports expanding the patient cap for buprenorphine treatment, and in fact urges the Department of Health and Human Services (HHS) to implement higher limits to meet the large and growing need. We also urge HHS to closely monitor implementation of any

[1] Department of Health and Human Services, Centers for Medicaid and Medicare Services, "Proposed Rule: Medication Assisted Treatment for Opioid Use Disorders (March 30, 2016) (available at https://www.federalregister.gov/articles/2016/03/30/2016-07128/medication-assisted-treatment-for-opioid-use-disorders).

[2] Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, "Mortality File Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014" (2015). Available at http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

[3] Paulozzi MD, Jones PharmD, Mack PhD, Rudd MSPH, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, "Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United State, 1999-2008" (2011).

[4] Feliz, Josie, Partnership for Drug Free Kids, "Survey: Ten Percent of American Adults Report Being in Recovery from Substance Abuse or Addiction" (2012). Available at http://www.drugfree.org/newsroom/survey-ten-percent-of-american-adults-report-being-in-recovery-from-substance-abuse-or-addiction.

changes made to determine if further expansions or changes are needed. Our views are detailed below.

Background

According to the National Institute on Drug Abuse, addiction to any drug – prescribed or illicit – is a brain disease that can be treated effectively. For addiction to prescription painkillers and other opioids, the treatment can include medications such as buprenorphine which can ease or eliminate withdrawal symptoms. Medication-assisted treatment (MAT) combines use of medications under doctor supervision along with counseling and participation in social support programs. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), MAT is often the best choice for opioid addiction.

Buprenorphine, which is one of three FDA-approved medications for MAT, is an opioid partial agonist with relatively low risk of misuse, dependency, and side effects.[5] Because buprenorphine can be prescribed from physicians' offices rather than dispensed from specialty clinics like methadone, it offers an important treatment option for many people experiencing opioid addiction.

The Drug Addiction Treatment Act of 2000 allowed physicians to become eligible to prescribe buprenorphine for opioid addiction.[6] A physician who meets certain licensing and training requirements and has the capacity to refer patients for appropriate supportive counseling and services can apply to treat up to 30 patients. After one year, the physician may request an increase to treat up to 100 patients.[7]

Currently, physicians are not able to treat more than 100 patients even when there is dire need, leaving many individuals without treatment, particularly in rural areas. As noted in the preamble to the proposed rule, out of the 2.5 million Americans who could benefit from MAT, only one million are receiving it. Further, in a 2015 survey by the American Society of Addiction Medicine (ASAM), two-thirds of responding physicians who are currently authorized to prescribe buprenorphine reported that demand exceeded 100 patients.[8]

Increasing the Patient Limit

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[5] SAMHSA, "Buprenorphine" (2015). Available at http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine.
[6] SAMHSA, "Drug Addiction Treatment Act of 2000." Available at http://buprenorphine.samhsa.gov/titlexxxv.html.
[7] *Id.*
[8] American Society of Addiction Medicine, "Survey Results: Addiction Specialists Weigh In on the DATA 2000 Patient Limits" (Dec. 7, 2015). Available at http://www.asam.org/magazine/read/article/2015/12/08/addiction-specialists-weigh-in-on-the-data-2000-patient-limits.

TFAH has worked with a range of partners and experts to identify promising policies and approaches to reducing prescription drug misuse in America. TFAH has recommended specific efforts to improve prescription drug monitoring programs, to expand public education, and to build community partnerships to address primary prevention.[9] Expanding access to treatment is a crucial component of these efforts, and the revision of the existing buprenorphine patient limit will help begin to address the treatment gap.

TFAH therefore strongly supports raising the buprenorphine patient limit. However, rather than set the new limit at 200 patients, we urge HHS to follow the expert views of the American Society of Addiction Medicine and raise the limit for all board-certified addiction specialists (including those certified by ASAM or by the American Board of Addiction Medicine, or ABAM) to 250 in the first year, and 500 patients thereafter; and to develop a training pathway for non-board-certified providers to treat at the same levels. We also urge HHS to consider the additional concerns raised by ASAM in their comments, in particular regarding the proposed "subspecialty" requirement.

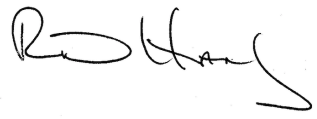
Regardless of HHS's ultimate decision on these policies, we urge HHS to closely monitor implementation of this change over the next year to determine what treatment gap still exists.

Conclusion

As noted above, access to medication-assisted treatment is only one piece of the solution to the opioid epidemic. A broad range of prevention and treatment interventions for both mental illness and substance use disorder must become more readily available to reduce morbidity and mortality from substance use disorder and mental illness. The proposed rule is a key step in supporting those efforts and making effective treatment for substance use disorder available for all Americans.

Thank you for your consideration of these comments. We look forward to a final rule that will expand access to substance misuse treatment and make a significant improvement in our nation's health. If you have any questions, please feel free to contact Becky Salay, TFAH's Director of Government Relations, at (202) 864-5945 or via email at bsalay@tfah.org.

Sincerely,



Rich Hamburg
Interim President and CEO

[9] TFAH, "Prescription Drug Abuse: Strategies to Stop the Epidemic," 2013 (available at http://healthyamericans.org/reports/drugabuse2013/TFAH2013RxDrugAbuseRpt12_no_embargo.pdf).