United States Senate
WASHINGTON, DC 20510

June 1, 2016

The Honorable Sylvia M. Burwell
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

As a nation, we must do more to combat the epidemic of opioid abuse that plagues communities across the United States. We appreciate the Administration's plans to address addiction through prevention, treatment, and enforcement efforts. As part of these initiatives, many of us have in the past urged you to use the authority granted to the Department of Health and Human Services (HHS) through the Drug Addiction Treatment Act of 2000 (P.L. 106-310) to increase access to medication assisted therapy (MAT) for the treatment of opioid abuse.

The current 100 patient cap is one of several factors that have created a huge disparity between those who can prescribe opioids for treatment of pain and those who can prescribe treatments for opioid use disorders. Only 10 percent of the 23 million Americans with addictions and substance use disorders receive any care in a given year.[1]

Addiction experts agree that individuals suffering from an opioid need access to a broad range of treatments, including MAT, which involves a combination of medications and therapeutic supports to help people recover from opioid use disorders. Furthermore, numerous studies have shown that MAT reduces drug use, disease rates, and criminal activity among individuals experiencing opioid addiction. Specifically, buprenorphine mono or combination therapy helps to reduce the transmission of HIV and hepatitis among drug users and the occurrence of high-risk injection practices.[2]

MAT has also been shown to be safe, cost-effective and reduce the risk of overdose. Wider use and greater accessibility will clearly reduce the societal and individual costs of this epidemic. MAT using drugs such as buprenorphine is also a critical treatment option from a patients'

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[1] Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings. NSDUH Series H-44. HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.; Substance Abuse and Mental Health Services Administration. (2013). Behavioral Health, United States, 2012. HHS Publication No. (SMA) 13-4797. Rockville, MD: Substance Abuse and Mental Health Services Administration.

[2] See, for example, Volkow, N., Frieden, T., Hyde, P., and Cha, S. Medication-Assisted Therapies-Tackling the Opioid-Overdose Epidemic. New England Journal of Medicine 2014; 370:2063-2066.

perspective because it allows individuals to maintain the structure of their everyday life while obtaining help with less stigma associated with the process.

While the proposed rule on MAT for opioid use disorders published by HHS on March 30, 2016, takes steps to increase access to buprenorphine, raising the cap to only 200 will be unlikely to make the meaningful impact needed in the marketplace to make buprenorphine a viable treatment option for patients. As you finalize the proposed rule, we strongly urge you to include a higher cap of 500 patients, consistent with the bipartisan compromise that emerged from the Senate Health, Education, Labor and Pensions (HELP) Committee last month with the advancement of S. 1455, *the Recovery Enhancement for Addiction Treatment (TREAT) Act*. This legislation also included provisions to allow nurse practitioners and physician assistants to provide MAT for opioid use disorders.

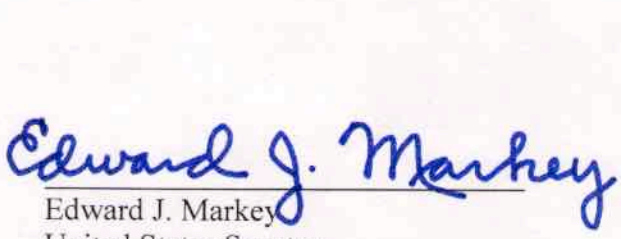
Concerns regarding diversion and misuse are valid, and protections can be put in place to minimize the behaviors of bad actors. In order to prescribe buprenorphine therapy, physicians must meet qualifications such as the completion of an eight-hour course and then apply for a special waiver. In our legislative effort, the Senate included additional requirements for prescribers in order to improve prescription practices and further reduce diversion. It is important, though, to balance these requirements with a high enough patient cap that prescribers will see a viable path forward in continuing to treat patients facing addiction and in becoming a bigger part of the treatment delivery system.

We recognize addressing buprenorphine access needs while preventing inappropriate use is a complex calculation and balance. The Department's actions should support our efforts with a patient cap that recognize the realities of how many patients it takes to have a viable provider practice, to invest in one's patients with quality improvements, and actively ensure less diversion.

Again, we appreciate the positive steps the Administration has taken to eliminate barriers to obtaining needed treatments such as buprenorphine. Together, we must do everything in our power to address our nation's opioid abuse epidemic. We ask you to take into account the bipartisan work of the Senate in advancing the TREAT Act and include in the final rule on medication assisted treatment for opioid use disorders a higher cap of 500 patients.

Sincerely,

Orrin G. Hatch
United States Senator



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