

United States Senate

WASHINGTON, DC 20510

August 7, 2015

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 you know, the United States is in the midst of a severe opioid abuse epidemic. In 2013 alone, approximately 1.9 million Americans met the diagnostic criteria for abuse or dependence on prescription pain relievers.¹ We support the Department's March announcement, which outlined a three-pronged approach to combat opioid abuse. We write today to urge you to use the full authority granted to the Department 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 use disorders.

While effective medications to treat opioid use disorders exist, federal regulations continue to limit access to these treatments. These restrictions have created a huge disparity between those who can prescribe opioids and those who can prescribe treatments for opioid addiction. Only 10 percent of the 23 million Americans with addictions and substance use disorders receive any care in a given year.²

Addiction experts agree that individuals suffering from an opioid use disorder need access to a broad range of treatments and services, including MAT, which typically involves a combination of medications and therapeutic supports to help people with opioid use disorders achieve recovery. Numerous studies have shown that MAT is cost effective, reduces drug use, disease rates, overdose risk and criminal activity among opioid addicted persons. For example, treatment with buprenorphine helps to reduce the transmission of HIV and hepatitis among drug users and the occurrence of high-risk injection practices.³

Medications such as methadone and buprenorphine benefit patients by reducing the side effects of withdrawal and curbing cravings, thereby assisting patients to achieve abstinence from their

¹ Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. NSDUH Series H-48. HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

² 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.

³ 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.

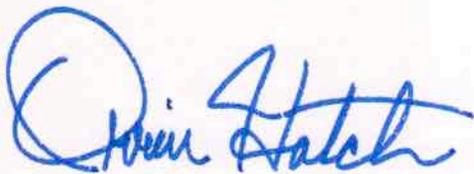
substance of abuse. Buprenorphine used alone or in combination with naloxone as an abuse deterrent formulation does not elicit a euphoric reaction in an opioid dependent patient and avoids the high risk of overdose associated with heroin and other opioids that are frequently misused and abused. Comprehensive MAT programs that include measures such as drug testing, the provision of behavioral counseling and other social services, implementation of anti-diversion measures, use of Prescription Drug Monitoring Programs, and reporting of drug use and treatment outcome measures help to ensure that quality care is provided to patients, while also reducing the risk of buprenorphine diversion.

Despite the effectiveness of MAT as one of the tools available to treat opioid addiction, there is significant under-treatment with this proven therapy. According to the National Survey on Drug Use and Health, of the 2.5 million Americans 12 years of age or older who abused or were dependent on opioids in 2012, fewer than one million received MAT.

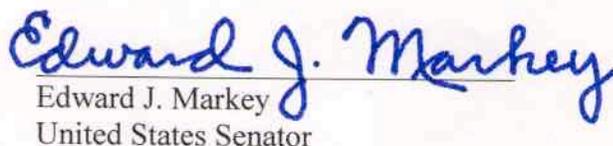
Use of buprenorphine is highly controlled. In order to prescribe buprenorphine therapy, physicians must take and pass an eight-hour course and meet other qualifications, and then apply for a special waiver. The Drug Addiction Treatment Act (DATA) was enacted to allow, for the first time, opioid addiction treatment in a primary care setting. This law arbitrarily capped the number of addicted patients a physician can treat at any one time to 30 through the first year and, if requested and certified, permits expansion to 100 patients thereafter. As an acknowledgement that the cap was set without a full understanding of what market use and application would be, the statute grants you as HHS Secretary direct authority to raise the cap. Lifting the cap under specific circumstances or other measures to increase access would enable physicians to treat more patients with these highly effective drugs and improve and increase access to quality and comprehensive opioid treatment programs. In addition, expanding the ability of other trained health professionals such as nurse practitioners and physician's assistants to practice as DATA providers merits consideration.

We view Administrative action to raise the current prescriber caps for providers in the appropriate practice environment for highly effective MAT medications such as buprenorphine therapy as an important part of larger collaborative efforts between the Congress and the Administration to address substance use disorders.

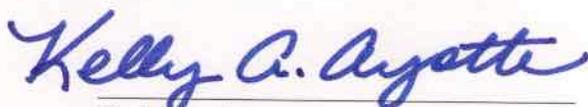
Sincerely,



Orrin G. Hatch
United States Senator



Edward J. Markey
United States Senator



Kelly A. Ayotte
United States Senator



Sherrod Brown
United States Senator

Shelley Moore Capito

Shelley Moore Capito
United States Senator

Susan M. Collins

Susan M. Collins
United States Senator

Dir Durbin

Richard J. Durbin
United States Senator

Dianne Feinstein

Dianne Feinstein
United States Senator

Mazie Hirono

Mazie Hirono
United States Senator

Angus King, Jr.

Angus S. King, Jr.
United States Senator

Mark Kirk

Mark Kirk
United States Senator

Rand Paul

Rand Paul, M.D.
United States Senator

Sheldon Whitehouse

Sheldon Whitehouse
United States Senator