AATOD
American Association for the Treatment of Opioid Dependence, Inc.

Expanding Access to Quality Opioid Addiction Treatment Services
since 1984

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August 13, 2014

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

Dear Secretary Burwell,

I am writing you pursuant to correspondence that you had received, dated June 26, 2014 from five US Senators. They were discussing their concerns about untreated opioid addiction in the United States, and indicated that the Department might have the ability to raise the patient cap for DATA 2000 practices without Congressional authorization.

I understand that the Department will be considering a number of policymaking initiatives in order to respond to the current public health crisis of untreated opioid addiction in our country, including the use of buprenorphine products in certified DATA 2000 practices and Opioid Treatment Programs (OTPs). At the present time, we have conducted a survey among the nation's State Opioid Treatment Authorities and AATOD member programs, concluding that buprenorphine is an underutilized medication in the OTPs based on the lack of reimbursement through third party payers.

We recognize that addiction to prescription opioids and heroin has been steadily increasing for a number of years. AATOD has been carefully tracking this phenomenon since January of 2005 in managing one of the RADARS™ Systems under the auspices of the Denver Health and Hospital Authority. More than 72,000 newly admitted patients have completed survey instruments at time of admission, with 45% of this patient number, indicating addiction to prescription opioids.

I am enclosing a policy paper, which our Association published on July 2, 2014. It discusses a number of important elements of any effective opioid addiction treatment strategy. In our judgment, the fact that we have such a complicated national public health problem, which took many years to develop, requires a combination of thoughtful solutions. It is inaccurate to think that this complicated problem will be resolved by simply lifting the existing cap of the number of patients that a SAMHSA approved, DATA 2000 practice can treat. As indicated in the policy paper, more OTPs and DATA 2000 practices need to open as a means of increasing access to care.

There should be consideration given to increasing the cap for DATA 2000 practices, when it has been clearly established that existing practices are at capacity. We recommend against any across the board lifting of the cap until we

know how effective these practices have proven to be in reducing drug abuse and treating related co-morbid conditions. Many DATA 2000 physicians prefer not to treat a large number of patients at their practices for several reasons, including anecdotal reports of feeling overwhelmed by treating patients with significant co-morbid conditions while they are also treating other patients as part of their general medical practice. We have also urged SAMHSA to conduct a survey of the approximately 7,500 certified DATA 2000 practitioners to determine how many medical practitioners have reached their 100 patient limit.

The enclosed paper also questions what we know about existing DATA 2000 practices and discusses some of the primary questions that should be asked and answered before any significant shift is made in federal policy. In our judgment, there is a reasonable question about how many opioid addicted patients can be effectively treated by a medical practitioner in a DATA 2000 practice. Can such a practitioner effectively treat between 250-500 patients, without proper clinical and administrative support personnel or without the ability to case manage the services that the patient should be receiving, based on all that we have learned in treating chronic opioid addiction over the past 50 years? In this regard, it is important to point out that SAMHSA is at the end stage of reviewing their draft and updated *Guidelines for the Accreditation of OTPs,* which were initially released on May 16, 2013. The initial draft provides 69 pages of extremely detailed administrative and clinical direction to the nation's certified OTPs concerning every conceivable aspect of treating chronic opioid addiction. These guidelines include a section on Diversion Control Strategies. No such counterpart applies to DATA 2000 practices, effectively creating a two-tiered system of treating this illness.

There are also innovative models being utilized in the states about how we maximize the use of existing treatment resources. The hub and spoke model in Vermont provides a case in point as Opioid Treatment Programs are also being opened as a means of providing increased access to care and creating referral opportunities between OTPs and DATA 2000 practices. We certainly think that the Department should consider a number of treatment initiatives, including having the Veteran's Administration have more medical practitioners' DATA 2000 certified to treat patients in VA settings in addition to having physicians certified in Federally Qualified Health Centers.

The enclosed paper has also recommended the consideration of adding midlevel practitioners as a new group of approved health care providers under the aegis of DATA 2000. Once again, if this were to happen, there would be a significant increase in the number of patients being treated with buprenorphine through a greater network of certified and trained practitioners. This would increase access to care without compromising the integrity of treatment services provided to each patient.

There has also been a public debate about what constitutes a therapeutic use of a diverted medication. A number of individuals have indicated that the vast majority of diverted buprenorphine is being used therapeutically by patients who cannot get access to care. As the paper indicates, this is a complex question that needs further exploration, prior to any significant shift in policy, as stated above, which may inadvertently increase buprenorphine diversion to the black market, which will not be used therapeutically.

Naloxone overdose prevention kits are being increasingly distributed to first responders in different cities and states in the country. The early results are promising and this should be a part of any solution to the crisis of increasing opioid addiction in this country. The enclosed policy paper also underscores the need to connect saving patients through such interventions to ongoing treatment. If this is not accomplished through coordinating service delivery systems, the beneficial results will be limited.

Finally, a third federally approved medication (Naltrexone/Vivitrol) is an underutilized medication. This medication can be used in general medical practice settings through a monthly injection. AATOD has published clinical guidelines to OTPs, encouraging the use of this medication as a relapse prevention tool.

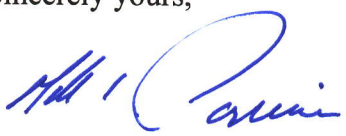
AATOD has been in existence since 1984 and represents 950 Opioid Treatment Programs (OTPs) in the United States and Mexico. AATOD is also the organizational co-founder with EUROPAD of the World Federation for the Treatment of Opioid Dependence. This worldwide federation was founded in 2007 and has Special Consultative Status with the United Nations. This World Federation provided guidance in the development of the World Health Organization's "Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence" (2009). It is useful to cite a reference from this WHO report, which discussed the benefits of medication assisted treatment for opioid addiction. "In the context of high quality, supervised, and well organized treatment services, these medications interrupt the cycle of intoxication and withdrawal, greatly reducing heroin and other illicit opioid use, crime, and the risk of death through overdose."

We have also worked with all federal and state agencies in the United States which have jurisdiction in this particular field. AATOD has continued to work with SAMHSA's leadership on a broad number of policymaking initiatives and we are extremely grateful for their efforts during such challenging times.

In closing, we recognize that this will be an ongoing policy discussion and urgent solutions are necessary. In our judgment, these solutions should be comprehensive, thoughtful, and based on what we have learned over the course of the past 50 years. We are urging the Department to work effectively with all of the federal and state agencies and other knowledgeable parties, which have a

stake in this policy matter. Once again, the simple solution of lifting the existing DATA 2000 cap without proper review of scope of services, as indicated above, is likely to create unintended and negative consequences. I look forward to future collaboration and thank you for taking these perspectives into consideration.

Sincerely yours,



Mark W. Parrino
President

CC: Pamela J. Hyde, J.D.
Administrator
Substance Abuse and Mental Health Services Administration

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