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

Expanding Access to Quality Opioid Addiction Treatment Services
since 1984

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May 20, 2016

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

Re: 42 CFR Part 8 RIN 0930-AA22
Medication Assistant Treatment for Opioid Use Disorders

Dear Secretary Burwell,

I am writing on behalf of the American Association for the Treatment of Opioid Dependence, which represents over 1000 SAMHSA licensed Opioid Treatment Programs (OTPs) in the United States. We are writing in response to the Federal Register Notice of March 30, 2016, which proposes to increase the number of patients in treatment in a DATA 2000 practice, which operates under the aegis of the Substance Abuse and Mental Health Services Administration.

> The purpose of this proposed rule is to expand access to Medication Assisted Treatment (MAT) by allowing eligible practitioners to request approval to treat up to two hundred patients under section 303 (g) (2) of the Controlled Substance Act (CSA). The rulemaking also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused and diverted. The rule also proposes a standard of care. Practitioners with the higher limit of 200 would also be required to accept greater responsibility for ensuring behavioral health services and care coordination are received and for ensuring quality assurance and improvement practices, diversion control, and continuity of care in emergencies.

Need for Increased Access to Medication Assisted Treatment

The Federal Register Notice clearly outlines the need for increased access to Medication Assisted Treatment for opioid addiction based on all that is known about the increasing abuse of prescription opioids and heroin. It took approximately thirty years for our country to get to the current public health

epidemic of opioid addiction. This letter will outline a number of policy making recommendations in response to the Federal Register Notice. It will cite what we have learned over the course of fifty years in treating opioid addiction and the necessity of following established standards of care with effective monitoring capabilities to ensure that patients are being treated according to their individual needs.

This letter is also consistent with what our Association has published through policy papers and correspondence over the last several years. Accordingly, the AATOD policy paper of July 2, 2014 "Increasing Access to Medication to Treat Opioid Addiction" will be cited in this response. We also wrote a letter to you on August 13, 2014 which referenced this particular paper and policy issue. Finally, we also submitted recommendations to SAMHSA on July 5, 2015, responding to the Federal Register Notice Vol. 80, No. 65 Notification Form (SMA-167). All of these communications will be referenced in this response. There are three major policy points, which are supported in this response.

- Effective treatment attends to multiple needs of the individual, not just his or her drug abuse. To be effective, treatment must address the individual's drug abuse and any associated medical, psychological, social, vocational and legal problems (NIDA)
- DHHS and SAMHSA should establish standards of care that DATA 2000 providers must follow
- DHHS and SAMHSA should establish a third party monitoring mechanism for DATA 2000 providers to ensure compliance with these standards.

The Early Rationale for Approving the Use of Buprenorphine and Other Scheduled III, IV, V Opioids in DATA 2000 Practices

It is important to reference the history of why Congress incorporated the initial restrictions of the thirty patient cap for DATA 2000 practices and the subsequent one hundred patient restriction. The federal government and members of Congress wanted to "normalize addiction medicine" by having a significant number of physicians treat a limited number of opioid addicted individuals as part of their private medical practices. The idea was to have integrated accessible care, so that patients could receive treatment for opioid addiction along with their medical care (e.g., treatment of hypertensive, diabetic, etc.) in a general setting. They did not wish to create more hub settings, such as opioid treatment programs, where a large number of patients would be treated in a specialized addiction treatment program. At the time, the public policy view was to eliminate the potential for regulatory oversight as long as such practices would treat a small number of patients.

This response to the FRN does not give any particular attention to the number of patients in treatment because each designated number is arbitrary by definition. Clearly, the early rationale has altered when measured against the backdrop of increasing opioid addiction since DATA 2000 was passed more than 15 years ago. I am also including a Patient Census Table for OTPs based on 2013 N-SSATS data. As you will note in reading the table, 50% of the nation's outpatient OTPs treated 250 patients or less in 2013. The focus of this response is about the quality of care that the patients should be receiving through Medication Assisted Treatment for opioid addiction. The Department and SAMHSA are changing the prior rationale for including addiction treatment as part of a general medical practice to specialized addiction treatment settings similar to an OTP. This shift also alters the policy making landscape to include established standards of clinical practice and the importance of third party monitoring to better ensure compliance with such standards.

Number of OTPs and Number of Patients (Methadone)				2013
Number of Patients	**OTPs**	**Percent**	**Cumulative OTP No.**	**Cumulative Percent**
1-24 patients	29	2.71	29	2.71
25-99 patients	122	11.41	151	14.13
100-249 patients	382	35.73	533	49.86
250-499 patients	358	33.49	891	83.35
500 + patients	178	16.65	1069	100

What is Medication Assisted Treatment for Opioid Addiction?

Part of the debate with regard to increasing access to treatment for opioid addiction focuses on the use of medications, which have been approved by the Food and Drug Administration (Methadone, Buprenorphine, Extended Release Naltrexone) to effectively treat opioid addiction when combined with other forms of therapy and medical care. The National Institute on Drug Abuse has made this point repeatedly in their Principles of Drug Addiction Treatment. "Effective treatment attends to multiple needs of the individual, not just his or her drug abuse. To be effective, treatment must address the individual's drug abuse and any associated medical, psychological, social, vocational and legal problems".

It is also important to reference SAMHSA's Treatment Improvement Protocol No. 43 (published 2005) with regard to treating opioid addiction as a medical disorder.

> Discussions about whether addiction is a medical disorder or a moral problem have a long history. For decades, studies have supported the view that opioid addiction is a medical disorder that can be treated effectively with medications, administered under conditions consistent with their pharmacological efficacy, when treatment includes comprehensive services, such as psychosocial counseling, treatment of co-occurring disorders, medical services, vocational rehabilitation services and case management services.

The point to referencing the NIDA and SAMHSA publications is to underscore that Medication Assisted Treatment is more than prescribing a medication alone. Many times over the course of the debate about using buprenorphine to treat opioid addiction through DATA 2000 practices, the importance of providing such services has been repeatedly marginalized.

What Do We Know About Medication Assisted Treatment through DATA 2000 Practices

In our communication of June 5, 2015 to Summer King of SAMHSA, responding to the Federal Register Notice Vol. 80, No.65 Notification Form (SMA-167) we made an important point about DATA 2000 practices.

> We believe that it is fair to state that SAMHSA does not currently collect adequate information about the care being provided within DATA 2000 practices. Illustratively, no one has any idea of how many patients are treated through DATA 2000 practices at any given point in time. No one has any aggregate data on what types of services are offered to patients, including counseling and other clinical support services, beyond the prescribing of Schedule III opioids to treat opioid addiction. No one has any idea if DATA 2000 practices are conducting toxicology testing to guide therapeutic decision making. No one has any centralized data collection with regard to DATA 2000 practices checking PDMP databases either prior to admitting the patient and throughout the patient's care.

This is still the case at the present time, which is why we support the general thrust of the Federal Register Notice to have DATA 2000 practices take greater responsibility to ensure that patients are getting more than a prescription for buprenorphine.

It is also important to reference an article by Dr. Adam J. Gordon "Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid

Program", which was published in the American Society of Addiction Medicine Publication Vol 9, No 6, Nov/ Dec 2015. "Increases in buprenorphine treatment in a Medicaid population were observed across time; however, increases varied by age, sex, and rate, and the quality of care received seemed to be generally poor". The article concluded "our study indicates that there may be quality-of-care concerns for patients receiving buprenorphine without a diagnosis of opioid use disorder that may contribute to diversion and/or accidental exposure of buprenorphine".

We believe that these points should be kept in mind as the Department of Health and Human Services and the Substance Abuse of Mental Health Services considers responses to this Federal Register Notice.

Brief History of Opioid Addiction Treatment in the United States and its Regulation

The use of Medication Assisted Treatment, exclusively methadone maintenance, increased sharply in the late 1960s and early 1970s in response to the crisis of untreated heroin addiction. There were increasing media and public health reports about heroin addiction primarily in large metropolitan cities through lower socio-economic groups. Methadone treatment programs were developed through a closed panel system following the FDA regulation of 1972. Methadone treatment programs opened quickly in different cities of the United States without the benefit of established clinical guidelines. As a matter of history, the first compendium of clinical guidelines would not be published until 1993 through SAMHSA's first Treatment Improvement Protocol "State Methadone Treatment Guidelines".

It is important to reference the United States General Accounting Office Report to the Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives. The GAO published its report during March 1990 "Methadone Maintenance-Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed". In spite of the fact that the Food and Drug Administration and the Drug Enforcement Administration had regulatory oversight for the methadone maintenance treatment program since 1972, the GAO report found that the FDA's oversight was lacking.

Subsequent to the publication of the GAO report, the Food and Drug Administration commissioned the Institute of Medicine to conduct a comprehensive review of Federal Regulations of Methadone Treatment program. The Institute of Medicine published its findings in 1995 and recommended that the Federal oversight of the methadone treatment programs change from a process oriented mechanism to a more patient outcome mechanism. The IOM also arrived at an important conclusion, which has relevance to this Federal Register Notice. "The committee concludes that a need

exists to maintain certain enforceable requirements in order to prevent substandard or unethical practices that have socially undesirable consequences".

The GAO report provided a number of critical recommendations which would guide future federal policy in this domain. "Standards should be based on results attainable from proven treatment approaches that combine appropriate doses of methadone and comprehensive rehabilitative services". The Report also concluded that "greater program oversight is needed and should be based on performance standards". Finally, The Report made a critical recommendation to federal agencies.

> To better monitor and assess methadone maintenance treatment programs we recommend that the Secretary of Health and Human Services direct the Food and Drug Administration or the National Institute on Drug Abuse, as appropriate, to : (1) develop result-oriented performance standards for methadone maintenance treatment programs, (2) provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of programs' performance, and (3) assure increased program oversight oriented toward performance standards.

There is another important reference that should be made in the context of what we know about treatment program characteristics. While Dr. John C. Ball and his associates published an article "Reducing the Risk of AIDS through Methadone Maintenance Treatment" in 1988 in the Journal of Health and Social Behavior, there were two findings that have particular relevance in this discussion. Dr. Ball and colleagues evaluated six methadone treatment programs in three Eastern cities during the course of the NIDA funded three year study. It is useful to cite these references.

> Although we had anticipated that there would be minor variations in outcome due to program differences, we thought that the dominant influence upon treatment success would be patients' characteristics, such as length of addiction, employment history, prior criminality and severity of psychiatric symptoms. This expectation was not substantiated by the research findings; instead we found program treatment variables to be of paramount importance in reducing IV usage.

Dr. John Ball's findings had a major impact on how federal authorities would provide oversight to opioid treatment programs.

> It is a major finding that some methadone maintenance programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates (especially long-term retention rates), high rates of scheduled attendance, a close, consistent and enduring

> relationship between staff and patients, and year-to-year stability of treatment staff. Conversely, the less effective programs are characterized by poor patient attendance, inadequate methadone medication, and high rates of staff turnover. Effective and ineffective programs, however, did not differ with regard to patient characteristics.

The bottom line point here is that the program characteristics are more important in determining patient outcome than pre-treatment patient characteristics.

SAMHSA's First Treatment Improvement Protocol- TIP #1

SAMHSA published its first TIP in 1993 "State Methadone Treatment Guidelines" responding to the critiques of the GAO report of 1990 and related policy interests as cited above. This TIP represented the first clinical comprehensive reference guide for the use of methadone in OTPs.

The proposed Federal Register Notice makes a reference to this kind of national guideline.

> In addition, this proposed rule would define "nationally recognized evidence based guidelines" to mean a document produced by a national or international medical professional association, public health entity, or governmental body with the aim of ensuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions. Such examples include The ASAM National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use; SAMHSA's Treatment Improvement Protocol 40; Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; the World Health Organization Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence" and the Federation of State Medical Boards' Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office.

AATOD agrees with making such standards of care required as a method of guiding clinical care in DATA 2000 practices. From our point of view, and based on the history of regulatory oversight of OTPs, such standards should be a required referenced point if physicians are going to treat opioid addicted patients through DATA 2000 practices. It cannot be a philosophic point of view; therefore, the DHHS and SAMHSA must find a way to incorporate the adherence of such standards as part of any guidance in how doctors will be treating patients with buprenorphine if they decide to treat more than one hundred patients at a single practice setting.

Additionally, it is recommended that such standards be required, with a third party monitoring mechanism to ensure that such standards of care are followed. History has demonstrated that compliance to voluntarily followed standards of practice are not adhered to without an established monitoring mechanism in the field of opioid addiction treatment.

The rationale for this recommendation is based on the history of how opioid treatment programs were regulated. As was already discussed, the GAO conducted an independent evaluation of twenty four methadone treatment programs in eight states in 1990. Following the release of the 1995 IOM report, the Department of Health and Human Services implemented a strategy to transition federal oversight from the Food and Drug Administration to the Substance Abuse and Mental Health Services Administration. After years of strategic development, this transition occurred in 2001. SAMHSA decided to use an accreditation oversight mechanism to monitor quality assurance in the OTPs primarily through the Joint Commission and CARF. Other accreditation entities such as The Council of Accreditation and the states of Washington and Missouri also became certified accreditation entities under the aegis of SAMHSA. One would argue that it would take several years of such surveys to better stabilize the quality of patient care in the OTPs.

While it was important for SAMHSA to publish its first Treatment Improvement Protocol in 1993, OTPs had the option to follow or ignore the clinical recommendations of the TIP. Accordingly, some treatment programs followed the recommended clinical guidelines while others chose not to. It would take the implementation of federal oversight through a SAMHSA accreditation mechanism, as referenced above, to create more consistent compliance with such clinical standards. Given this documented history, the DHHS and SAMHSA need to consider the standardization and monitoring of medical practices for DATA 2000 practices. Only in this way will patients get access to care beyond the prescription of a medication.

While the Federal Register Notice makes reference to developing diversion control guidelines, checking prescription drug monitoring databases, making clinical referrals, and evaluating patient outcome; this is not likely to occur unless there is some mechanism to better track compliance to such recommendations. If a mechanism is not established, the Federal Government is likely to repeat the experience, as cited above, of OTPs.

The Public Health Safety of Diverted Buprenorphine.

There has been a fair amount of debate about the concerns of illicitly used buprenorphine products when diverted through the black market. Generally speaking, when such medications are diverted they are typically prescribed by

some practitioner through legitimate means. The individual patient will not use the medication for their own use and will subsequently sell or divert the medication for illicit means. Buprenorphine diversion is also related to the theft of the product. The public health debate goes along the following path: we should not be concerned about such diverted medication at a time of untreated opioid addiction because it is better for the individual to misuse buprenorphine than heroin.

Another element in this debate is the reason for such buprenorphine diversion. This argument proceeds along the following lines. If there were more practitioners treating patients with buprenorphine through Medication Assisted Treatment, there would be far less diverted buprenorphine. The same argument was made about methadone maintenance in the 1960s and more treatment programs opened. As such programs opened and more methadone became available through take home medication, there were reports of diversion until better take home practice standards were developed and followed. While there was methadone diversion in the 1970s and 1980s, it would take years to decrease such methadone diversion rates. Unfortunately, there was considerable damage done to the perceived integrity of the methadone maintenance treatment system as a direct result of this diversion.

While the DHHS and SAMHSA question how diversion programs could be established in the propsed rule through DATA 2000 practices, the Department should evaluate SAMHSA's March 2015 Diversion Control Plans for OTPs as a reference guide.

There is a third element to the buprenorphine diversion debate, which focuses on the "therapeutic use" of misused buprenorphine. It is important to keep in mind that buprenorphine is an opioid which is subject to abuse. The way to counter the abuse of buprenorphine is to have the medication properly used by the patient and monitored through any approved opioid treatment provider whether it is an OTP or a DATA 2000 practice. In our judgment, an untreated opioid addicted individual uses illegally procured opioids in a way that does not contribute to the stability of care. The individual will access whatever drug he/she can get when they are experiencing withdrawal as a result of their opioid addiction. There is no therapeutic relationship to a provider when such opioids are misused by someone who is opioid addicted. This point is made by a former chief medical officer to SAMHSA "Dr. Elinore McCance-Katz" in the August 11, 2014 edition of Alcoholism and Drug Abuse Weekly. "If your body requires opioids in order not to go through a painful withdrawal, and if you can find one through street use that will last longer, you may prefer it. Is that therapeutic? I would say no. Buying buprenorphine on the street is not therapeutic". We agree with this perspective.

It is also useful to reference a study, conducted by Dr. Theodore J. Cicero "Factors Contributing to the Rise of Buprenorphine Misuse: 2008-2013", as

published in Drug and Alcohol Dependence (42, 98-104). This study uses extensive data collected by the RADARS® System (Researched Abuse, Diversion and Addiction-Related Surveillance System) as managed by the Denver Health and Hospital Authority. Dr. Cicero is the Principal Investigator for one of the RADARS® System Programs (SKIP- Survey of Key Informants). Dr. Cicero and his colleagues found that one-third of buprenorphine users reported injecting the drug in the prior month before entering treatment, which represents a public health concern for the transmission of hepatitis C, HIV and other infectious diseases. Dr. Cicero's study also reached an important conclusion, which is related to this policy debate.

> Our results demonstrate that the misuse of buprenorphine has increased substantially in the last 5 years [2008-2013], confirming and extending earlier reports of such increases (Drug Enforcement Administration, 2009; Substance Abuse and Mental Health Services Administration and Drug Abuse Warning (DAWN), 2011; Unites States Department of Justice and National Drug Intelligence Center (NDIC), 2011; Wish et al., 2012; Lavonas et al., 2014). Certainly, much of this increase has been fueled by an increase in the therapeutic us of buprenorphine, which was accelerated by the release of generics in 2009. Given that it has been shown that there is a direct correlation between the extent of therapeutic use and diversion to street use (Cicero et al., 2007 a, b; Lavonas et al., 2014), increases in buprenorphine misuse are not unexpected.

It is important to keep in mind how our nation got into the current state of untreated opioid abuse and addiction. It is now well established that physicians, however well meaning, contributed to this crisis by not properly monitoring their patients when such individuals were prescribed opioids to treat pain in the general medical practice setting. This is not a criticism as much as it is a fact. Accordingly, if we are to properly treat chronic opioid addiction in the United States, then we need to break the cycle of poor monitoring of patients as they are prescribed opioids, whether that is treating pain or addiction. The recently released CDC guidelines on pain management provide an important reference point.

There is also another point that needs to be addressed. If Buprenorphine misuse was safe, why are there so many individuals being admitted to emergency rooms as a direct result of the non-medical use of buprenorphine? The University of Maryland has published a number of reports in their CESAR FAX Series which have expressed this concern. The University of Maryland released a CESAR FAX on July 4, 2011 (Vol. 20 Issue 25) focusing on Emergency Department Visits Related to Non-Medical Use of Buprenorphine.

> The estimated number of emergency department visits related to the non-medical use of buprenorphine more than tripled from 2006-2009,

> according to data from Drug Abuse Warning Network (DAWN). In 2006, the non-medical use of buprenorphine was involved as either a direct cause or a contributing factor in an estimated 4,440 emergency department visits, compared to 14,266 in 2009. These increases parallel increases in the number of law enforcement-seized buprenorphine items analyzed by state and local forensic laboratories.

The University of Maryland released another CESAR FAX report on March 5, 2012 Vol. 21, Issue 9 about "Warning of Emerging Epidemic of Buprenorphine Misuse". "Although the therapeutic benefits of buprenorphine treatment are well substantiated, it is important to recognize the unintended consequences of newly introduced analgesics, which have historically taken years to address. We need to act quickly to avoid suffering such consequences again".

The point in citing such references is to challenge the myth that misused buprenorphine can be used therapeutically by untreated opioid addicted individuals. The very nature of this particular disease does not allow many individuals to safely use any unmonitored opioid during a time of untreated addiction.

The Value of Clinical Care in Support of Medication to Treat Opioid Addiction

It is useful to reference an early perspective on this matter of clinical care through Dr. Vincent Dole, who with his associates, Dr. Marie Nyswander and Dr. Mary Jeanne Kreek, developed the foundation of methadone maintenance treatment at Rockefeller University in the mid 1960s. Dr. Dole's point on this matter is captured in the book, Addicts Who Survived: An Oral History of Narcotic Use in America, 1923-1965.

> The problem was one of rehabilitating people with a very complicated mixture of social problems on top of a specific medical problem, and that (practitioners) ought to tailor their programs to the kind of problems they were dealing with. The strength of the early programs as designed by Marie Nyswander was in their sensitivity to individual human problems. The stupidity of thinking that just giving methadone to solve a complicated problem seems to me beyond comprehension.

We agree with this perspective and AATOD's policy recommendations have reflected these principles since our founding in 1984. AATOD also supported NIDA's Principles of Drug Addiction Treatment based on years of evidence based practices in treating opioid addiction. We have also agreed with the SAMHSA Treatment Improvement Protocols and Guidelines, which seek to ensure that patients get proper care in treating opioid addiction.

ASAM's National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use and published in 2015 provide another benchmark reference. Based on the long history of opioid addiction treatment and its oversight, which was referenced above, we do not think that such guidelines should only provide a suggestion for practitioners, which can be ignored or followed at will.

Another debate has recently arisen with regard to the value of clinical care. There are some articles that question the utility of providing counseling to patients in addition to medications for opioid addiction. The argument is framed by these articles which indicate that there is no significant difference when counseling is used or not used in conjunction with medication. So, how do we know when clinical care is useful? The same way we might know that the treatment providers have the knowledge and training of what they are doing. Illustratively, if the clinician is under-trained, lacking in knowledge and lacking in compassion, they are not likely to provide any good quality recovery support for the use of any medication in treating opioid addiction whether that medication is methadone, buprenorphine or extended release naltrexone. Conversely, if a clinician is well trained, has the necessary knowledge to treat addiction and is also compassionate in not judging the individual but helping the individual, then such clinical care will provide an important adjunct to the use of medications. The point here is not to disclaim the value of counseling, which has been established over the course of many years and why we make reference to Medication Assisted Treatment for Opioid Addiction. The point is to have the clinician as well trained as possible to be a part of an effective treatment network.

Summary

While the DHHS and SAMHSA are working to increase access to the treatment for opioid addiction, it is important to keep the principles, as referenced above, in mind as such policies are implemented. We need thoughtful mechanisms in place in order to increase such access to care so that we get our nation out of the current public health crisis of untreated opioid addiction. While the focus of this Federal Register Notice is an increase in the number of patients in the DATA 2000 practice, there is also a need for better models of integrated care working between OTPs and DATA 2000 practices and other primary and behavioral healthcare settings. There also needs to be an organized effort on the part of the federal government to expand access to OTPs wherever they are needed. There needs to be a better and more sustained reimbursement for such treatment through third parties either through public funding or commercial insurers. There also needs to be a better national educational campaign, explaining to American citizens when they are getting into trouble when misusing/ abusing their prescription opioids.

From AATOD's perspective, increasing the number of patients in treatment is a part of the solution. It is important to ensure that patients receive evidence-based care in support of stabilizing and recovering from the ravages of long term opioid addiction. Policy makers must take into account the law of unintended consequences with any immediate policy fix. Opioid addiction is a complicated disease and is treatable when medications are used with other interventions, as noted above and based on many years of evidence.

It is our hope that these considerations will be taken into account as the Department and SAMHSA finalizes the terms of how more patients can have access to care through DATA 2000 practices.

Sincerely yours,

Mark W. Parrino
President

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