ASAM The Voice of Addiction Medicine
American Society of Addiction Medicine

Testimony of Robert Corey Waller, MD, MS
Before the Energy and Commerce Committee Subcommittee on Health
October 20, 2015

Executive Summary

My name is Dr. Corey Waller, and I'm the Chair of the Legislative Advocacy Committee of the American Society of Addiction Medicine (ASAM), which represents more than 3,700 of our nation's addiction specialist physicians and other clinicians.

My testimony today will focus on the following facts:

1. Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.
2. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

Opioid addiction is taking a devastating toll on our families, friends and neighbors across the country, but there is hope when patients can access effective treatment services. ASAM is honored today to offer its thoughts and expertise on how we can close the treatment gap, improve the quality of care, and ultimately save lives.

Written Statement

Chairman Pitts and Ranking Member Green, thank you very much for inviting me to participate in this important hearing. I'm grateful to you and the other Members of the Subcommittee for your leadership in addressing the epidemic of opioid addiction currently ravaging our country.

My name is Dr. Corey Waller, and I am the Chair of the Legislative Advocacy Committee of the American Society of Addiction Medicine, also known as ASAM. This testimony is offered on behalf of ASAM, myself as a practicing addiction specialist physician, and my patients, who are unable to speak before this committee themselves. I am board certified in both addiction medicine and emergency medicine, and I'm the Medical Director of the Spectrum Health Medical Group Center for Integrative Medicine, the Medical Staff Chief of Pain Medicine to the Spectrum Health Hospital System, as well as Substance Use Disorder Medical Director at Lakeshore Regional Partners in Grand Rapids, MI.

Established in 1954, ASAM is a national medical specialty society of more than 3,700 physicians and allied health professionals, including a growing number of nurse practitioners and physician assistants. Its mission is to increase access to and improve the quality of addiction treatment; to educate physicians, other health care providers and the public; to support research and prevention; and to promote the appropriate role of the physician in the care of patients with addictive disorders.

My testimony today will focus on the following three facts:

1. Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.

2. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

Addiction is a Chronic Brain Disease

We're here today to provide recommendations on how best to respond to the epidemic of prescription opioid and heroin misuse, addiction and related overdose deaths, which, according to the Centers for Disease Control (CDC), have reached epidemic levels in our country. We've all seen the data and heard the shocking statistics. But what's not said or heard enough is that the 2.3 million people who need treatment for opioid addiction have a chronic disease of the brain. While we need to prevent other Americans from developing addiction, these 2.3 million people need treatment.

Like other chronic diseases, such as hypertension and diabetes, addiction is the result of a combination of biological (genetic) and environmental factors. Rather than affecting the circulatory or endocrine system, however, addiction affects areas of the brain involved in reward, motivation and memory, and leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, cravings, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction

often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

Also like other chronic diseases, addiction can be treated, but it requires long-term management. Historically, we've treated addiction in this country acutely, expecting patients to recover after relatively short stints in detox or rehabilitation programs. Unfortunately, this model of care isn't working, and it's putting patients at heightened risk for overdose when they return to their communities with a reduced opioid tolerance.

Instead, these patients need ongoing chronic disease management, the goal of which is to reduce morbidity and mortality related to their disease, improve functioning, and use the lowest dose of medication possible. Rather than considering whether or not a patient still needs medication to manage his or her illness, we should be looking for treatment outcomes like reduced incidence of infectious disease, increased employment, housing stability, and reduced involvement with the criminal justice system, among other indicators of a return to physical, mental, social and spiritual health.

Addiction Involving Opioid Use Can Be Treated Successfully

These outcomes are not unattainable for a person suffering from opioid addiction. Indeed, addiction involving opioid use can be treated successfully with a combination of medication and psychosocial services.

There are currently three medications that are FDA-approved to treat opioid addiction: methadone, which has been used in highly regulated opioid treatment programs since the 1960s; buprenorphine, which has been used since 2002 by physicians who complete a special

training in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber.

All of these medications have proven to be clinically effective. A 2013 review of the scientific literature found substantial, broad and conclusive evidence for the effectiveness of all three medications, and for methadone in particular.[1] Notably, the literature on the efficacy of these medications is not new - there are now eight large-scale, rigorously conducted, reviews of the literature on these medications since the early 1980's. In particular, treatment with methadone has been shown to reduce opioid use, criminal justice involvement, drug-related deaths, unemployment and HIV risk behavior. Several studies of office-based treatment with buprenorphine have found it improves treatment engagement; reduces cravings, illicit opioid use, and mortality; and improves psychosocial outcomes. While there were comparatively fewer studies of naltrexone available at the time of the review, the available research did suggest that it is safe, generally well tolerated and results in immediate and complete blockade of opioid receptors and thus discontinuation of self-administered opioids. Additional research is needed to determine whether early experience with extended-release injectable naltrexone, which suggests greater retention in treatment, reduced craving, and lower opioid use, will result in greater patient willingness to continue the monthly injections and the protection from opioid relapse afforded by those injections. It's important to note, as we consider how to expand access to these medications, that naltrexone cannot be administered to pregnant women; only methadone and buprenorphine are safe to use with expectant mothers.

Finally, we have clear and comprehensive guidelines for how to use these medications effectively in the clinical care of persons with addiction. ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* was developed to promote evidence-based clinical treatment of opioid use disorder and to assist physicians in the

decision-making process for prescribing pharmacotherapies to patients with opioid use disorder. It's the first guideline to address all the FDA-approved medications available to treat addiction involving opioid use and opioid overdose - methadone, buprenorphine, naltrexone and naloxone. The guideline offers specific clinical recommendations on the assessment and diagnosis of opioid use disorder, treatment options, managing withdrawal, initiating treatment and switching between medications, psychosocial treatment, and special considerations for populations such as pregnant women, adolescents, and persons involved in the criminal justice system.[2]

There are Significant Barriers to Access these Medications Leading to a Major Treatment Gap

However, despite the strong evidence base for the use of these medications and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Less than 30% of treatment programs offer medications and less than half of eligible patients in those programs receive medications.[3] Indeed, a study published just last week in the Journal of the American Medical Association found that 80% of Americans with opioid addiction don't receive treatment.[4]

This treatment gap is attributable to many factors, some more complex than others. Research has demonstrated significant access barriers to methadone, including waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the OTP daily.

The Drug Addiction Treatment Act of 2000 (DATA 2000) was intended to expand access to addiction treatment across geographies and populations by integrating it into the general

medical setting. However, there are also barriers to accessing buprenorphine, including provider willingness and limited insurance coverage. Particularly among specialists like myself and other physicians with advanced training in the treatment of addiction, the limit on the number of patients an individual physician can treat with buprenorphine is a significant barrier to access. ASAM surveyed its members regarding their buprenorphine prescribing practices, in 2013. The results illustrate the difficulties even addiction medicine specialists are having in meeting patient demand. Over 90% of respondents reported having a DEA waiver to prescribe buprenorphine to at least 30 patients with three quarters of those prescribing buprenorphine certified to treat up to 100 patients. However, nearly half reported patient demand in excess of 100 individuals.

In recent months my practice has had to turn away many patients due to the 100 patient limit for buprenorphine. This includes pregnant patients as well as the children of my friends and has resulted in at least 2 overdose deaths. If I am out of town or unavailable, my Physician Assistants are unable to see the patients who need an urgent intake, due to the restrictions on PAs and NPs writing for buprenorphine, which exists even if they are under the guidance of a physician who is board certified in Addiction.

It's important to note that the entire purpose of DATA 2000 was to make opioid addiction treatment available outside OTP settings in traditional physicians' offices, both to increase access in areas where OTPs may be physically inaccessible and to reduce the stigma and patient burden associated with visiting an OTP for treatment on a daily basis. Federal regulation of OTPs is significant, as is state oversight of these facilities. For example, these facilities are required to employ counselors and must be accredited by the Joint Commission or CARF. Regulating individual physician practices in such a manner would undoubtedly overburden smaller practices and drive individual physicians away from offering addiction treatment

services, reducing the already-limited addiction treatment workforce and exacerbating the treatment gap.

This is not to say that the quality of office-based buprenorphine treatment services available is of uniformly high quality. We recognize that diversion of buprenorphine is a problem in many areas and agree that it's a concern. Moreover, due to lack of insurance coverage or lack of qualified providers, some patients don't receive high quality psychosocial support in addition to their medication. That's why our recommendations to lift the patient limits under DATA 2000 include required training on diversion control techniques such as call-backs, pill counts and urine drug screens, as well as comprehensive education on psychosocial supports.

While increased diversion is often cited as a chief concern related to raising the patient limit, research suggests that the relationship between treatment access and diversion is an inverse relationship, meaning greater access may even reduce diversion. Highlighting this is a study out of the University of Kentucky that found an inability to access treatment was a risk factor for using diverted buprenorphine.[5] This finding aligns with what many addiction treatment providers know from experience: when patients cannot access treatment, either due to wait lists or lack of insurance, they may purchase diverted buprenorphine to self-medicate. Additionally, some patients will share their prescription with loved ones who cannot access treatment or sell part of their prescription to cover the expense of the office visit for their addiction treatment if their insurance coverage does not pay for (or does not pay adequately for) the physician's services or the cost of the medication.

Still, because diversion and quality of care remain legitimate concerns, ASAM has proposed a gradual and limited lifting of the DATA 2000 limits. Our recommendations would allow specialists and physicians with additional training to treat up to 500 patients, while being subject

to quality checks by SAMHSA (See Attachment 1). Specifically, ASAM proposes that either Congress or the Secretary of the Department of Health and Human Services (HHS) increase the limit as follows:

- Over a two-year phase-in, increase the limit for prescribing physicians to 250 patients in year 1 and 500 patients in year 2. Prescribers seeking an increase in patient limit must satisfy additional addiction treatment training requirements approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) that covers prescribing, counseling, treatment planning, drug testing, pill recall, etc. This training would be in addition to the buprenorphine certification requirement currently required to qualify for the 30/100 patient prescribing limit.

- Prescribing physicians who are expert in treating addiction as evidenced by board certification by ABAM in addiction medicine or the American Board of Psychiatry and Neurology (ABPN) in addiction psychiatry shall not be required to obtain the additional training, including training on diversion control techniques and psychosocial interventions.

- Additionally, we recommend there be a follow up study on the impact of increasing the limit on diversion rates and treatment access. Specifically, after year 2 of the increased prescribing limit, HHS, in consultation with the Drug Enforcement Administration (DEA), and CDC, should determine what impact, if any, the increase in access to opioid addiction medications has had on: decreasing deaths due to opioid overdose; decreasing diversion rates; and improving patient access to the Food and Drug Administration (FDA)-approved opioid addiction pharmacotherapies.

By coupling a lifting of the patient limit with increased training requirements and accountability for those physicians treating large numbers of patients, we feel we can expand access while also ensuring a certain quality of care. Still, this single strategy should be just one part of broader federal efforts to ensure safe prescribing of opioids for pain, alternate pain therapy options and early identification of and treatment for addiction.

Pain and addiction education should be required curriculum in medical school and encouraged as continuing medical education throughout a physician's career. Communities should have the resources to educate their citizens about these issues and the outreach and surveillance resources necessary to better understand their unique issues and needs.

Thank you, again, for the opportunity to present here today. ASAM looks forward to a continued collaboration on this and other addiction-related issues.

###

[1] Chalk M, Alanis-Hirsch K, Woodworth A, Kemp J, and McClellan T. FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness & Cost- Effectiveness. 2013. Available at: http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

[2] Kampman K and Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med* 2015;9: 1–10.

[3] Abraham AJ, Knudsen HK, Rieckmann T, Roman PM. Disparities in access to physicians and medications for the treatment of substance use disorders between publicly and privately funded treatment programs in the United States. *J Stud Alcohol Drugs*. 2013 Mar;74(2):258-65

[4] Saloner B and Karthikeyan S. Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013. *JAMA.* 2015;314(14):1515-1517.

[5] Lofwall, M.R. and Havens, J.R. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug Alcohol Depend.* 2012 Dec 1;126(3):379-83.

Appendix: ASAM Position on Bills under Consideration

Bill	ASAM Position
HR 2536, the Recovery Enhancement for Addiction Treatment Act	ASAM strongly supports this bill as a means of improving patient access to life-saving medications that treat opioid addiction through a strategy that supports improved prescriber education, diversion control and expansion of qualified buprenorphine treatment providers. The current opioid epidemic is compounded by a documented gap in access to evidence-based treatment, including buprenorphine treatment. Expanding the prescribing limit for qualified addiction treatment providers will have an immediate, positive impact on expanding opioid addiction patient access to a clinically and cost-effective addiction pharmacotherapy. ASAM has also recommended an approach to expand the DATA 2000 patient limits that would gradually increase the limits for board-certified specialists and other physicians who have completed additional training requirements (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter). These recommendations propose expanding the patient limit to 250 in the first year of prescribing and 500 thereafter. Physicians prescribing to more than 100 patients under this approach would be subject to random audits by SAMHSA to ensure they are adhering national standards of care and national medical

	practice guidelines for the treatment of opioid addiction with agonist, partial-agonist and antagonist medications (for example, the establishment of individual treatment plans; use of individual, family and group psychosocial services; and use of diversion control strategies). This recommended approach would also expand prescribing authority to nurse practitioners and physician assistants who complete additional training (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter) and practice under the supervision of a physician qualified under these recommendations to treat more than 100 patients.
HR 2805, the Heroin and Prescription Opioid Abuse Prevention, Education and Enforcement Act	ASAM supports this bill but notes that the section directing the establishment of a Pain Management Best Practices Inter-Agency Task Force to develop best prescribing practices may be redundant to efforts currently underway by the CDC. Still, ASAM supports the reauthorization of the Byrne Justice Assistance Grant program, the advancement of public education and awareness campaigns, and the development of naloxone demonstration grants to improve naloxone access.
HR 2872, the Opioid Treatment Modernization Act	ASAM has several concerns with this bill and believes it will have significant unintended consequences on access to addiction treatment involving buprenorphine. Dramatically reducing access to evidence-based addiction treatment at a time when our nation is experiencing an epidemic of prescription opioid and heroin overdose deaths is misguided

	policy. This bill would create several new barriers to treatment by placing unnecessary and excessive administrative burdens on physicians to prescribe buprenorphine, as well as by creating new, additional barriers to becoming certified to prescribe this medication in the first place. In effect, it would reduce the addiction treatment workforce and further restrict already limited access to care for patients in need, particularly in rural and underserved areas where there are already access issues. Moreover, since the bill only amends the section of the Controlled Substances Act governing the use of Schedule III-V narcotics to treat addiction in physicians' offices, it by default only applies to the use of one of the three FDA-approved medications for opioid addiction treatment. It therefore will not be able to have its intended effect of ensuring "the full range of science- and evidence-based treatment options for opioid addiction are fully integrated into treatment," because it narrowly targets only one treatment option.
HR 3014, the Medical Controlled Substances Transportation Act	ASAM is concerned this bill would create significant loopholes that could be exploited by those wishing to transport controlled substances for illicit purposes and undermine local law enforcement agencies' ability to interrupt drug trafficking.
HR 3537, the Synthetic Drug Control Act	ASAM supports the careful regulation of dependence-producing substances. Additionally, ASAM recommends that

	law enforcement measures aimed at interrupting the distribution of illicit drugs should be aimed with the greatest intensity at those causing the most serious acute problems to society. The balance of resources devoted to combating these problems should be shifted from a predominance of law enforcement to a greater emphasis on treatment and prevention programs, as well as programs to ameliorate those social factors that exacerbate drug dependence and its related problems. ASAM would also recommend either a delayed effective date or additional funding for DEA to process research approvals for those scientists currently conducting research on these specific substances.
HR 3680, the Co-Prescribing to Reduce Overdoses Act	ASAM supports efforts to increase co-prescribing of naloxone to patients receiving high-potency, long-acting opioids, so that naloxone is available for home use in the event of an overdose situation experienced by the patient or by any others in the household.
Draft Bill, the Improving Treatment for Pregnant and Postpartum Women Act	ASAM supports efforts to increase access to opioid addiction treatment services for pregnant and postpartum women.

Attachment 1: ASAM Letter to Secretary Burwell, July 31, 2014

July 31, 2014

The Honorable Sylvia Burwell
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell,

On behalf of the members of the American Society of Addiction Medicine (ASAM), the nation's largest medical professional society representing addiction physician specialists and affiliated addiction health professionals, we respectfully submit to you our recommendations for urgently addressing the opioid epidemic. These recommendations are informed by our members' collective expertise and reflect their myriad specialty backgrounds, the diverse patient populations they serve, and the wide range of clinical settings in which they practice.

Opioid addiction does not discriminate: regardless of income, education level or social standing, opioid addiction looks the same to the practicing addiction doctor. It leads to severe impairment and, far too often, to death. Fortunately, like other chronic diseases, opioid addiction can be prevented and the millions of Americans now suffering from this disease can be treated. As with other chronic illnesses, treatment does not consist of only one simple treatment for all sufferers. Treatment often requires multiple, overlapping therapies that may include medication, behavioral therapy, family therapy, and ongoing recovery support.

With that framework in mind, we urge the Administration to consider proposals that focus holistically on provider and community education, overdose death prevention and increased access to treatment, in order to effectively manage the epidemic. We hope the following recommendations inform and support the critical work you are doing to address this issue.

Sincerely,

Stuart Gitlow, MD, MPH, MBA, FAPA
President, American Society of Addiction Medicine

Attachment: ASAM Recommendations to Address the Opioid Epidemic

CC:
Pamela Hyde, JD, Administrator, Substance Abuse and Mental Health Services Administrator (SAMHSA)
Elinore McCance-Katz, MD, PhD, Chief Medical Officer, SAMHSA
H. Westley Clark, MD, JD, MPH, Director, SAMHSA Center for Substance Abuse Treatment
Michael M. Botticelli, Acting Director, Office of National Drug Control Policy

Overdose Prevention and Opioid Addiction Treatment Recommendations

Section I: Education

Physicians receive little training about pain management or addiction treatment in medical school or in residency programs. As a result, there is a general lack of understanding and experience among most physicians related to these diseases. This lack of education reinforces the prevailing modes of practice: prescription opioids for pain management and an antiquated view of addiction as an acute behavioral problem for which treatment is only self help or weeks of inpatient rehabilitation.

It is the opinion of ASAM that a lack of education among most physicians about the proper treatment of chronic pain and chronic opioid addiction disease is a considerable contributing factor to the current opioid addiction epidemic. ASAM offers the following recommendations, in an effort to address these problems:

1. Mandatory prescriber education on addiction prevention/treatment tied to DEA certificate to prescribe controlled substances.

a. Applies to all prescribers of controlled substances including, but not limited to, physicians, nurse practitioners, and physician assistants, as well as to pharmacists.
b. Education would also be required for recertification.

2. Mandatory medical school education on addiction (minimum 12 hours)
    a. Schools not in compliance with requirement would be unable to accept students using federal financial aid
3. Community Education Grants on proper use of naloxone, and the continuum of care for treatment of addictive disease

Section II: Prevention

Building on the infrastructure of the Drug Free Communities (DFC) program is a cost effective way to invest minimal federal dollars to prevent prescription drug abuse at the community level and get positive results. ASAM recommends:

1. New funding to allow current and past DFC grantees to apply for supplemental grants of up to $75,000, on a dollar for dollar matching basis, to deal with their community's prescription drug epidemic in a comprehensive, community wide fashion. ($5 million)

Section III: Overdose Prevention

ASAM supports the increased use of naloxone in cases of opioid overdose. Naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal harmful side effects, when used to prevent the often fatal respiratory arrest which characterizes the advanced stages of prescription or illegal "opioid" overdose. Naloxone can be

administered quickly and effectively by trained professionals and by lay individuals who observe the initial signs of an opioid overdose.

Persons provided with naloxone supplies for use in the event of drug overdose, including known illicit opioid users who are provided with these supplies under a public health program of harm reduction, should be educate about the prevention, detection, and appropriate response to drug overdose, for example, how to recognize opioid overdose symptoms and how to refer to emergency medical services. Lay persons offered prescriptions for naloxone at medical visits, or provided with nasal naloxone delivery devices through public health agencies, should also be provided education on proper use of these devices and information on accessing addiction treatment.

Therefore, ASAM recommends:

1. Increase naloxone access with recommended training including: pharmacist training; package inserts appropriate to the patient's level ; and/or community-based training and education about both opioid overdose treatment and about opioid addiction treatment options.

Section IV: Treatment

A key mission statement of the American Society of Addiction Medicine is, "to increase access to and improve the quality of addiction treatment." A 2013 survey of ASAM's membership revealed that the 100-patient prescribing limit on buprenorphine was considered a major barrier to patient access to care. Furthermore, ASAM public policy specifically recommends against laws, regulations or health insurance practices that impose arbitrary limits on the number of

patients who can be treated by a physician or the number and variety of pharmacologic and/or psychosocial therapies that may be used for treatment. No other disease, no other specialty, and no other medication are limited in this manner.

Fundamentally, the following recommendations are intended to address an escalating opioid epidemic by addressing a policy that significantly limits patient access to a clinically and cost-effective treatment by proposing alternatives that would increase access to pharmacotherapies to treat opioid addiction in a thoughtful, judicious way.

ASAM's recommendations are also supported by the development of an ASAM clinical guideline on pharmacological therapies for opioid use disorders that will establish very clear boundaries around the proper use of buprenorphine in managing opioid addiction, including strategies for mitigating diversion like the establishment of treatment plans and routine random drug screens, pill counts, and prescription drug monitoring program reviews. Recognizing that best practice of chronic diseases requires attention to all elements of a biopsychosocial approach, the guideline also specifically addresses the utility of psychosocial supports in the treatment plan by doing a literature review of all the existing clinical evidence regarding these modalities in the context of medication management of opioid addiction.

Given these considerations, ASAM recommends:

1. Increase of buprenorphine prescribing limit, phased in over 2 years (250 patient limit per physician for year 1, then a 500 patient limit per physician for year 2)
    a. Prescribing physicians who are expert in treating addiction as evidenced by addiction medicine certification by the American Society of Addiction Medicine (ASAM), board certification in addiction medicine by the American Board of Addiction Medicine (ABAM) , subspecialty board certification in addiction

psychiatry from the American Board of Psychiatry and Neurology (ABPN), or a subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) shall qualify for an increased limit, to 250 in year 1 and 500 in year 2.

b. Non-addiction specialist physicians seeking an increase in patient limit must satisfy additional addiction treatment training requirements as follows:
    i. Additional training requirements for non-addiction physician specialists will be developed by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Osteopathic Academy of Addiction Medicine, or any other organization that the Secretary determines is appropriate for purposes of this subclause, in consultation with the Substance Abuse and Mental Health Services Administration (SAMHSA).
    ii. Such training will consist of a minimum of 40 hours including both didactic and skills-based training based in the standards of high quality care using buprenorphine, as delineated in national medical practice guidelines related to the treatment of opioid addiction with pharmacotherapy (ASAM practice guidelines, to be released in Spring 2015).
    iii. Training must include at least 2 hours each, in the following areas:
        1. The chronic disease of addiction
        2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
        3. 12 step models of recovery
        4. Individual, group and family education and counseling
        5. Motivational enhancement theory and skill development
        6. Contingency management techniques

7. Development and use of treatment plans
8. Use of and interpretation of drug screens and tests
9. Diversion control: random call backs, drug screens, and medication counts
10. Medical and Psychiatric comorbidities and the coordination of care
11. Use of prescribed or illicit drugs of abuse while in buprenorphine treatment: integrating the roles of PDMPs, care coordination, contingency management, treatment plans, family sessions, and the continuum of care
12. Medico-legal and ethical issues in addiction treatment with buprenorphine

c. Advance-practice providers (APPs, e.g., nurse practitioners, physician assistants) who meet the requirements to obtain a waiver to prescribe buprenorphine can only do so under the supervision of a physician who is certified to treat over 100 patients (see #1a, 1b above)
    i. APPs may not exceed the 100-patient limit.
    ii. APPs must complete the training course as described in 1b above in order to prescribe buprenorphine to treat addiction.
    iii. The 100 patients treated by an APP will not be counted as part of their supervising physician's limit.
d. All prescribers are required to complete 36 hours of continuing medical education related to addiction medicine every 3 years.
    i. Physician specialists, as defined in 1a, could be waived from the ongoing education requirement if they can prove ongoing participation in their board's Maintenance of Certification requirements.

ii. Physicians practicing under the 100-patient limit would be required to satisfy 9 hours of continuing medical education related to addiction medicine, every 3 years.

2. All practitioners who are certified to treat 250 or 500 opioid-dependent patients with buprenorphine may be subject to random site audits by the Substance Abuse and Mental Health Services Administration (SAMHSA), in order to assure that high-level prescribers are adhering to national addiction medicine standards of care and to national medical practice guidelines related to the treatment of opioid addiction with opioid agonist, partial-agonist and antagonist pharmacotherapies.
   a. Audits by SAMHSA shall be in lieu of audits by the Drug Enforcement Administration (DEA).
   b. Practitioners prescribing to over 100 patients who do not comply with a SAMHSA audit will be subject to an audit by the DEA.
   c. Physicians prescribing within the parameters of the 30-patient and/or 100-patient waiver will not be subject to SAMHSA or DEA audits.
   d. Non-physician prescribers shall be subject to audit as part of the audit of their physician supervisors.
   e. In order to meet audit requirements, prescribers should include the following, as part of their office-based opioid treatment program protocols:
      i. bio-psycho- social admission assessments, including appropriate physical examination and laboratory testing
      ii. Formal treatment planning and regular treatment plan updates
      iii. Screening for medical and psychiatric co-morbidities and referral for treatment

iv. Utilization of individual, family, and group psycho-education and counseling modalities consistent with guidelines and treatment of other chronic behavioral health disorders

v. Utilization of both scheduled and random drug screens, scheduled and random drug tests when appropriate, and Prescription Drug Monitoring Program checks

vi. Use of contingency management protocols, with repercussions for failed drug screens/ failed PDMPs consistent with harm-reduction treatment of opioid dependence approach

3. Follow-up study on impact of increase on diversion rates (DEA) and impact on treatment access (HHS/ASPE).
   a. There is evidence indicating that geographic areas of low access to buprenorphine treatment have higher levels of buprenorphine diversion. After year 2 of the increased prescribing limits, HHS, in consultation with the DEA, will determine what impact, if any, the increase in access to opioid addiction medications has had on diversion rates and whether there has been improved patient access to the FDA-approved opioid addiction pharmacotherapies.

4. Remove restriction on initiation of buprenorphine for the treatment of opioid addiction in hospitals.
   a. Under current regulations, physicians who initiate patients for the first time on buprenorphine for the treatment of opioid addiction in hospitals are unable to have the prescription filled by a hospital inpatient pharmacy. Hospitals are currently being told, in writing, that they cannot let their inpatient DEA registration

and their inpatient medication administration procedures apply to the initiation of buprenorphine for opioid addiction.

5. $50 million in increased Substance Abuse Prevention and Treatment block grant funding for dissemination of evidence-based models for preventing and treating opioid dependence

American Society of Addiction Medicine
4601 North Park Avenue • Upper Arcade Suite 101 • Chevy Chase, MD 20815-4520
PHONE: (301) 656-3920 • FACSIMILE: (301) 656-3815
E-MAIL: EMAIL@ASAM.ORG • WEBSITE: HTTP://WWW.ASAM.ORG