American Society of Addiction Medicine

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Treat Addiction ● Save Lives

July 31, 2014

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

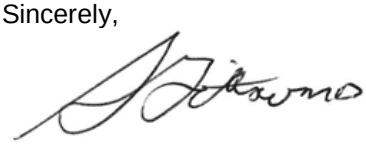
Dear Secretary Burwell,

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,



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Attachment: ASAM Recommendations to Address the Opioid Epidemic

CC:
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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