**TITLE: STUDY OF FEDERAL STANDARD 42 CFR §8.12 FOR OPIOID TREATMENT PROGRAMS**

**WHEREAS:**

Federal regulation 42 CFR §8.12 outlines opioid treatment standards in the United States. The standards were established in 2001 and have subsequently been amended on three occasions (2003, 2012 and last updated in 2015). The standards for opioid treatment programs (OTPs) include details regarding the administrative and organizational structure, continuous quality improvement, staff credentials, patient admission criteria, required services, assessments, counseling services, testing services, record-keeping and patient confidentiality, medication administration, dispensing, and use.[1] Fatal overdose, hospitalization due to overdose, and diagnosis of Opioid Use Disorder has been increasing since the early 2000's.[4] All-cause mortality when an individual is receiving treatment is less than half that observed after treatment is discontinued.[4] In a recent multistate study of addiction treatment and retention in care, less than 25% of youths diagnosed with OUD received timely, medication-assisted treatment.[4] The American Psychiatric Association is uniquely positioned to take into consideration national developments in the field of opioid treatment, assess the current guidelines and provide recommendations to bring them in line with current standards of care.

Since federal regulation was last amended in 2015, there have been major changes in best practices for opioid treatment. The guidelines make reference to outdated standards, namely DSM-IV. The overall impact of the DSM-5 changes on the field of Addiction is not entirely clear. There is also a general lack of clarity in areas related to leadership responsibility, level of training and education required for Medical Directors of OTPs. As the APA has stated in a position statement, "the treatment with medication of patients with mental illness requires a foundation of medical education, training, supervision, and care of patients with a broad range and severity of medical problems."[3] It would serve to benefit patients if federal standards specified what training was required of its staff, including the position of Medical Director. The definitions of patients that qualify for maintenance treatment are not clearly established and are restricted to those with a one-year history of addiction. Moreover, persons under 18 are required to have two documented unsuccessful attempts at short-term detox within a 12 month period and supporting parental/legal guardian consent.

Current policies and procedures do not reflect accommodation of special patient populations, nor do they protect patients who are vulnerable to treatment discontinuation. Women in methadone treatment frequently lack access to information and services that support them in achieving their reproductive goals. Women who develop endocrine dysfunction as a result of their opioid use (including methadone use) may experience a decrease in fertility, however not necessarily infertility. They have higher rates of unplanned pregnancy and lower rates of contraceptive use.[5] Guidelines do not mandate on-site availability of prenatal care, availability of STD prophylaxis and contraceptives including condoms, oral contraception, or Plan B. Furthermore, they do not mandate on-site, free, and on-demand HIV testing. Finally, premature discharge from a medication-assisted treatment program is associated with higher rates of relapse and mortality, subsequent treatment admissions, HIV/AIDS, and

legal problems.[6] Federal guidelines should take this into consideration, and make only the most egregious violations of clinic policy grounds for termination from the program.

**BE IT RESOLVED:**

That a workgroup be formed to propose amendments to the 42 CFR 8.12 and make recommendations for changing federal guidelines related to opioid treatment standards. These changes should address, but not be limited to, use of DSM-5 terminology, defining credentials and training requirements for staff leadership positions such as that of Medical Director, adding accommodations for special patient populations such as pregnant women, minors, and persons with physical disabilities, and ensuring on-site access to STD testing/prevention services and prenatal care.

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**KEY WORDS:** OPIOID USE DISORDER, OPIOID TREATMENT PROGRAM, METHADONE, BUPRENORPHINE,

**APA STRATEGIC PRIORITIES:** Education

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