FOR IMMEDIATE RELEASE
April 27, 2021

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Statement from the American Society of Addiction Medicine on
HHS Practice Guidelines Exemption from Enumerated X-Waiver Certifications
For Eligible DEA-Registered Practitioners

The new policy exempts eligible, DEA-registered practitioners from federal certification requirements related to training, counseling, and other ancillary services that are part of the process for obtaining a waiver to treat up to 30 patients with buprenorphine – a step toward helping Americans with opioid use disorder access evidence-based addiction care.

Rockville, MD - The American Society of Addiction Medicine (ASAM) applauds steps to reduce barriers to patients accessing medications for opioid use disorder (OUD), including today’s announcement from the U.S. Department of Health and Human Services (HHS) on Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, which were posted for public inspection in the Federal Register today.

“The guidelines released by HHS create exemptions from enumerated X-waiver certifications with respect to certain practitioners prescribing buprenorphine for opioid use disorder, an important step toward improving our patients’ access to this medication,” said Dr. William Haning, president of ASAM. “We now look to Congress to take critical and necessary next steps, including securing a permanent elimination of buprenorphine-specific training requirements, patient limits, and DEA audits, as well as the separate X-waiver application, for DEA-registered prescribers, while ensuring these clinicians receive baseline training on treating patients with substance use disorder.”

From 1999 to 2017, nearly 400,000 people in the United States died from overdoses related to opioids – due in part to a critical misunderstanding of the substantial evidence for the safety and effectiveness of medications that treat OUD, as well as the historical separation of addiction treatment from mainstream medical care.

Specifically, the new HHS practice guidelines exempt eligible, DEA-registered practitioners from the certification requirements under 21 U.S.C. §823(g)(2)(B)(i)-(ii). The exemption, however, is
subject to the limitations of the guidelines. For example, a practitioner utilizing this exemption will still be required to obtain a waiver by submitting a Notice of Intent to the Substance Abuse and Mental Health Services Administration before treating patients with buprenorphine for OUD. Such a practitioner also will be limited to treating no more than 30 patients with buprenorphine for OUD at any one time, and time spent practicing under the exemption will not qualify the practitioner for a higher patient limit. Finally, while these guidelines change certain federal requirements, they do not govern possible state requirements that may be applicable.

ASAM notes that an elimination of the X-waiver should be combined with needed education about the identification and treatment of substance use disorder in patients seen in daily practice. Proper education increases clinicians’ willingness to administering life-saving, addiction care. ASAM commends HHS for recognizing that substance use disorder education is not yet uniformly integrated into medical education and that colleges of medicine and training programs are strongly encouraged to develop or to continue implementing comprehensive training in substance use disorder diagnosis and management as a component of their core, required curriculum.

“While the ongoing COVID-19 pandemic has wrought havoc on all, it has particularly jeopardized the health of vulnerable populations, including the more than 20 million Americans living with substance use disorder,” said Dr. Haning. “An elimination of the X-waiver coupled with increased addiction training has the potential to save thousands of lives and free DEA-registered prescribers of unnecessary barriers that have too long impeded them from helping their patients.”

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**About the American Society of Addiction Medicine**
The American Society of Addiction Medicine (ASAM), founded in 1954, is a professional medical society representing over 6,600 physicians, clinicians and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention and promoting the appropriate role of physicians in the care of patients with addiction. For more information, visit [www.ASAM.org](http://www.ASAM.org).