Published on *The National Law Review* https://natlawreview.com

# Proposed Rule Seeks to Increase Access to Treatment for Opioid and Heroin Abuse

Article By:

Eric J. Plinke

Daniel S. Zinsmaster

In a continuation of the Federal government's focus on the opioid and heroin epidemic, ***President Barack Obama*** announced last week that the ***United States Department of Health and Human Services (HHS)*** has issued a proposed rule intended to increase the number of patients a qualified physician may treat using Buprenorphine for opioid and heroin addiction.[i] If implemented, the change would increase access to medication-assisted treatment and behavioral health support for the tens of thousands of people currently suffering from opioid use disorders but unable to gain access to treatment providers. As such, the proposed rule was quickly praised by the American Society of Addiction Medicine, who has long-advocated raising or eliminating the patient limitation for Buprenorphine prescribers.

Currently, in order to use *Buprenorphine* products for the purpose of treating opioid and heroin addiction, a physician must apply and qualify for a special registration under the ***Drug Addiction Treatment Act of 2000*** (see 21 U.S.C. 823(g)). An approved physician is then provided with a unique registration number that must be included on every prescription. Under the current Federal law, an approved physician cannot treat more than 100 patients for opioid maintenance treatment and must attest that he or she has the capacity to refer addiction treatment patients for appropriate counseling and other non-pharmacologic therapies.

The common Buprenorphine products of Suboxone or Subutex – combinations of Buprenorphine and Naloxone – are available in tablet and film formulations that require self-administration by patients on a daily basis. Both medications work to eradicate the influence opioids have on the brain, and allow those dependent upon opioids and heroin to stop taking drugs without experiencing painful withdrawal symptoms or struggling with drug cravings. Additionally, the U.S. Food and Drug Administration is reviewing a product named Probuphine, an investigational subdermal implant designed to deliver Buprenorphine continuously for six months following a single treatment. Conceivably, such Buprenorphine product could promote greater levels of patient compliance and retention with treatment programs.

The proposed rule from HHS seeks to increase the limitation placed on appropriately trained and qualified physicians from 100 patients to 200 patients, thereby increasing a physician's ability to

incorporate such treatment modality into their practice. While still only a proposal at this point, President Obama's comments indicate considerable support by the executive branch to facilitate greater access to drug treatment. The Substance Abuse and Mental Health Services Administration is accepting official comments from the public through May 31, 2016.

i *See* Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 17,639 (March 30, 2016) (to be codified at 42 C.F.R. pt. 8).



National Law Review, Volume VI, Number 95