

HHS Releases New Reporting Rules for Opioid Addiction Practitioners

According to the [U.S. Centers for Disease Control and Prevention](#), almost

million Americans died of opioid addiction/drug overdoses from 2000-2014. Since 1999, the overall number of overdose fatalities involving some type of opioid (including heroin and prescribed pain medications) increased by nearly fourfold. More than six out of ten deaths by drug overdose involve opioids. And to this day, the average number of Americans who die from an opioid overdose is 78 daily.

Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements

The government's efforts in combating the opioid epidemic include new reporting requirements for healthcare practitioners approved to treat up to 275 patients in an office setting for opioid addiction that will go into effect later this month.

Coming on the heels of President Obama's designation of September 18-24, 2016 as Prescription Opioid and Heroin Epidemic Awareness Week, the U.S. Department of Health and Human Services (HHS) released the rule entitled "Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements."

The new requirements are specifically for practitioners using Buprenorphine products (like Suboxone and Subutex) to treat addiction to heroin or opioid drugs, and they follow a change in federal law that raised the patient maximum from 100 to 275 for each practitioner, providing s/he meets certain conditions. Practitioners approved for the higher patient ceiling bear additional responsibilities, and the new reporting requirements have been designed to determine compliance to those demands.

Rule focuses on three categories of reporting

The new reporting requirements center around three types of information:

- 1) Yearly patient caseload (broken down by month)
- 2) Number of patients given or referred to mental health services
- 3) Specific components of the practitioner's diversion control plan

HHS has not yet stipulated hard-and-fast rules for diversion control plans, but broadly, it has indicated that the plans should include strategies for reducing the risk that controlled substances provided to patients will be used illicitly or transferred to individuals whom they have not been prescribed. Before a practitioner can be approved to operate under a patient limit of 275, s/he must have a diversion control plan in place.

Annual anniversary date reporting



Practitioners will be required to submit their report to the Substance Abuse and Mental Health Services Administration (SAMHSA) within 30 days of the anniversary date of the practitioner's official approval for seeing the maximum 275 patients allowed. Participating healthcare professionals may also be asked to include additional documentation and supporting data with the annual report.

Guidance from HHS on how to calculate the figures for each of the reporting requirements is forthcoming (HHS says it will be released before the rule goes into effect on October 27th.)

The Opioid Initiative continues to unfold

These reporting requirements are the newest addition to HHS's Opioid Initiative begun in March of 2015. The initiative is the government's response to the country's opioid epidemic and focuses on broadening access to medication-assisted healthcare for opioid use disorder, making opioid prescribing practices safer and more effective, and bumping up the use of the drug Naloxone as a reversal to opioid overdoses.

Practitioners should be aware that non-compliance with these new reporting requirements may trigger rescindment of SAMHSA's approval of the practitioner's increased patient allowance. And of course, this will likely not be the final piece of regulatory guidance from the government as it continues to develop additional oversight for the treatment of opioid use disorder.

For more information/questions regarding any legal matters, please email info@nelsonhardiman.com or call 310.203.2800.