

## **HHS Issues New Reporting Requirements for Practitioners Treating Opioid Addiction**

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Just days after President Obama announced September 18 – 24, 2016, as Prescription Opioid and Heroin Epidemic Awareness Week, the U.S. Department of Health and Human Services (HHS) issued new reporting requirements for practitioners who have been approved to treat up to 275 patients using Buprenorphine products, such as Suboxone and Subutex, in an office setting for opioid and heroin addiction. The rule, entitled “Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements,”<sup>[i]</sup> follows recent changes in federal law raising the patient limit from 100 to 275 patients per practitioner if the practitioner meets certain conditions. The reporting requirements were issued to assess compliance with the additional responsibilities imposed on those practitioners who are approved for the increased patient limit.

The new rule requires practitioners report three categories of information: (1) annual caseload of patients by month; (2) number of patients provided or referred to behavioral health services; and (3) features of the practitioner’s diversion control plan. While specific requirements for diversion control plans have not been provided, the plans should include procedures calculated to reduce the possibility that controlled substances will be transferred or used illicitly. HHS has emphasized the importance of diversion control plans by requiring practitioners to have a control plan in place before they are eligible to receive approval to increase their patient limit to 275.

Practitioners must submit their report to the Substance Abuse and Mental Health Services Administration (SAMHSA) within 30 days of the anniversary date of the practitioner’s approval for an increased patient limit. Practitioners may also be required to submit supporting data and documentation along with the annual report. HHS will release guidance on how to calculate the numbers for each reporting requirement prior to the rule going into effect on October 27, 2016.

The reporting requirements are the most recent addition to the “Opioid Initiative,” launched by HHS in March 2015 as part of the resident’s response to the opioid epidemic. The initiative is focused on improving opioid prescribing practices, expanding access to medication-assisted treatment for opioid use disorders, and increasing the use of Naloxone to reverse opioid overdoses.

Failure to comply with the new reporting requirements may result in withdrawal of SAMHSA’s

approval of the practitioner's increased patient limit. As the federal government continues to promulgate new regulations regarding treatment for opioid use disorders, we will continue to monitor and provide updates regarding such developments.

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[i] See Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements, 81 Fed. Reg. 66191 (September 27, 2016) (to be codified at 42 C.F.R. § 8.635).

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