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Prescriber Beware: Federal Enforcement Focuses on Drug Treatment Clinics

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March 2017

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Like pain clinics and pharmacies, practitioners treating substance use disorder appear to be a target for federal enforcers. Under President Trump's administration and Alabama Attorney General Steve Marshall, law enforcement is not expected to let up. Medication assisted treatment for addiction (MAT) is not a new source of regulation or enforcement, but practitioners have noticed a renewed focus there, along with some confusion.

As of the deadline for this article, two Mobile physicians remain on trial for alleged misconduct in operating their pain management practice and pharmacy. Additionally, on February 7, a Huntsville physician described by prosecutors as “a licensed drug dealer” was sentenced to 18 years of prison and supervision, \$13.4 million in restitution, plus other penalties and abandonment of his license and clinic. Alabama's new Attorney General, Steve Marshall, has also been fighting the opioid epidemic for years and will make it a priority.

MAT clinics or “methadone clinics” have been proven safe and effective for decades, when provided in conjunction with counseling. Since 2002, buprenorphine (e.g., Bunavail, Suboxone, Zubsolv) has been approved for use by prescription outside of a methadone clinic, in an office-based setting. More than 100 Alabama physicians are now credentialed to prescribe buprenorphine. Nurse practitioners and physician assistants may also now train and become qualified. Patients with substance use disorder now have increased access to care; thus, regulators and enforcers have an increased number of providers on radar.

Practitioners in these clinics fall into multiple categories where rules can become confusing even to the federal enforcers. Some practitioners only work in a certified opioid treatment program (OTP), where only methadone is dispensed. Some of these also prescribe buprenorphine. Others see patients at outpatient clinics where buprenorphine is only prescribed. Still others prescribe and dispense - but only buprenorphine. Collectively, these prescribers of buprenorphine are called “DATA-waiver practitioners” because the Drug Addiction Treatment Act of 2000 (DATA 2000) allows for the application of a waiver for specialized prescription privileges that comes with receipt of what is called the “X Waiver”, which is a separate number from the Drug Enforcement Administration (DEA) with the prefix "X". Many of them are either semi-retired or splitting time with a separate medical practice or multiple MAT clinics, even across state lines. All of the varying situations are legal

but present complex compliance issues that make it difficult for practitioners and clinics to rely on word of mouth advice or an internet search, just as the same doesn't replace a medical degree.

OTPs must apply to the Substance Abuse and Mental Health Services Administration (SAMHSA), to become certified and accredited. Practitioners who treat substance use disorder with buprenorphine (whether through an OTP or not) must apply to SAMHSA for an X Waiver. SAMHSA is an agency of the US Department of Health and Human Services for behavior health with a mission "to reduce the impact of substance abuse and mental illness on American communities." DEA is the federal enforcer.

Practitioners in an OTP should ensure it is certified and accredited (at least provisionally as it works to become accredited within a year) and remains current, and that their work there is properly under the clinic's DEA registration. OTPs have their own unique state and federal registration and updating requirements.

Outpatient clinics treating substance use disorder must not only have their practitioners' credentials on file but should ensure they remain current at DEA and SAMHSA - correct address, clinic name, telephone number, and current state credentials. Updates may be made online. These websites have known glitches, so after making changes online it's advised to log out or exit, not log back in the same day, and wait a day or two to verify the changes. Clinics not only benefit from helping new and current physicians stay updated, but also by ensuring departed physicians no longer list the clinic as a place of business. A new certificate should be issued upon acceptance of the modifications, and both the original and new certificates must be maintained until expiration.

To treat substance use disorder in multiple states, separate state credentials, separate DEA registrations, and special care are required. Practicing at multiple locations within a state requires separate DEA registrations for each location unless operating under the hospital/clinic's or OTP's registration or only prescribing and not dispensing at the other locations. DATA-waiver practitioners may prescribe or dispense buprenorphine outside of a methadone clinic, but dispensing at multiple locations requires separate DEA registration. With an X Waiver and a DEA registration for writing prescriptions within a particular state, a practitioner may prescribe buprenorphine at multiple clinics without additional DEA registrations. The X Waiver applies across state lines and across clinics, but SAMHSA expects to have all current clinic locations listed.

Patient limits vary by physician. Federal regulations limit the practitioner to a number of patients with active prescriptions of buprenorphine, whether 30 or 100 or now up to 275. The limit does not include patients treated in a methadone clinic, but having the X Waiver, alone, does not qualify a physician to treat an unlimited number of patients with buprenorphine across multiple clinics or states.

In Alabama and many other states, MAT is governed by a regulatory set of model guidelines for accepted professional practice. Following these guidelines is a good start, and that includes keeping

copies of prescription orders in the medical record. DEA may review these records and suggest the patient's date of birth is required on prescriptions, but it is not required in Alabama - even if it is a common and appropriate practice.

DEA may also suggest the practitioner surrender her license without contacting an attorney. MAT is necessary, safe, and effective, but it is highly regulated. As such, consulting a lawyer should not be viewed as suspicious. Practitioners should not be intimidated or discouraged from obtaining sound legal advice to safely navigate a regulatory environment in order to apply their education, training, and experience to faithfully serve a community in need.

Routine DEA audits should not cause a panic. Remain calm and respectful. Politely ask at any time to consult with an attorney, and call a health care lawyer. Many issues may be resolved administratively with professional legal guidance. The law is constantly changing in this area, so consider making legal review part of a routine annual check-up.



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