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**TRIAGE: RAPID LEGAL LESSONS FOR
BUSY HEALTH CARE PROFESSIONALS**



The Opioid Epidemic:
Federal and State Requirements on
Medication-Assisted Treatment for
Substance Abuse Disorders

Lauren G. Perry

MEDICATION-ASSISTED TREATMENT (“MAT”)

- FDA-approved medications for substance abuse disorders:
 - Methadone
 - Buprenorphine
 - Naltrexone
- Providers of MAT
 - Opioid Treatment Programs (“OTP”)/Narcotic Treatment Program
 - Practitioners through office-based opioid treatment (“OBOT”)

OPIOID TREATMENT PROGRAMS

- OTPs are regulated by the Substance Abuse and Mental Health Services Administration (“SAMHSA”).
- Governing regulations – 42 C.F. R. Part 8
- OTPs must have:
 - Accreditation by SAMHSA-approved body
 - Certification by SAMHSA
 - DEA Registration
- As part of the federal requirements, OTPs must assure patients have access to adequate medical, counseling, vocational, educational, and other assessment and treatment services by providing the services themselves or through contracting with an entity to perform.

OPIOID TREATMENT PROGRAMS

- State Requirements – vary by state.
- Almost all states also require OTPs to be licensed, typically by the drug and alcohol agency in the state.
- Example: Pennsylvania requires OTPs to be licensed by the Department of Drug and Alcohol Programs. Licensure requires inspection by the agency.

OFFICE-BASED OPIOID TREATMENT (“OBOT”)

- Drug Addiction Treatment Act of 2000 (“DATA 2000”)
 - Allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV and V narcotic medication in settings other than OTPs.
 - Known as OBOT
 - Physicians must be approved for the waiver and complete the required training.
- Comprehensive Addiction and Recovery Act (“CARA”)
 - Expanded DATA 2000 to allow qualified nurse practitioners and physician assistants to also prescribe.
 - Expanded the maximum number of patients a physician can see for opioid treatment under the waiver from 100 to 275 patients.
- State Regulations
 - Recently some states have begun to regulate OBOTs.

Today's Presenter



Lauren G. Perry
 New York/Harrisburg
 +1.212.536.3956
 lauren.perry@klgates.com

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Health care is one of the largest and most heavily regulated industries and touches on every life stage and condition. Because each sector of the health care industry has its own unique rules and standards for operation, navigating the minefield of regulations and other rules can be especially challenging. Articles in this section address the full range of issues faced by companies operating in the health care and pharmaceutical fields.

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