Definition of a 42 CFR Part 2 Program

To be a “program” that falls under 42 CFR Part 2, an individual or entity must be federally assisted and hold itself out as providing, and provide, alcohol or drug abuse diagnosis, treatment or referral for treatment (42 CFR § 2.11). A program is “federally assisted” if it is:

1) authorized, licensed, certified, or registered by the federal government (https://findtreatment.samhsa.gov/);
2) receives federal funds in any form, even if the funds do not directly pay for the alcohol or drug abuse services; or
3) is assisted by the Internal Revenue Service through a grant of tax exempt status or allowance of tax deductions for contributions; or
4) is authorized to conduct business by the federal government (e.g., certified as a Medicare provider, authorized to conduct methadone maintenance treatment, or registered with the Drug Enforcement Agency (DEA) to dispense a controlled substance used in the treatment of alcohol or drug abuse); or
5) is conducted directly by the federal government.

A different definition of a “program” applies when services are provided by a specialized unit or staff within a general medical facility. A general medical facility has a Part 2 program if:

1) there is “an identified unit within a medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment;” or
2) there are “medical personnel or other staff in a general medical facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.” (42 CFR § 2.11 (b), (c)) Most drug and alcohol treatment programs are federally assisted. However, there are for profit programs and private practitioners that may not receive federal assistance of any kind. These programs and practitioners only see clients who have private health insurance or self-pay. Unless the State licensing or certification agency requires those programs or private practitioners to comply with Part 2, they are not subject to the requirements of 42 CFR Part 2, because they are not federally assisted. States may, however, enact laws requiring compliance with Part 2, and programs should refer to their state laws in these situations. Clinicians who use a controlled substance (e.g., benzodiazepines, methadone or buprenorphine) for detoxification or maintenance treatment of a substance use disorder require a federal DEA registration and become subject to Part 2 through the DEA license. In contrast, a physician who does not use a controlled substance for treatment, such as Naltrexone, and does not otherwise meet the definition of a Part 2 program is not subject to Part 2.