

qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

#### § 8.2 Definitions.

The following definitions apply to this part:

*Accreditation* means the process of review and acceptance by an accreditation body.

*Accreditation body* means a body that has been approved by SAMHSA under § 8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

*Accreditation body application* means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in § 8.3(b).

*Accreditation elements* mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

*Accreditation survey* means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in § 8.12.

*Accredited opioid treatment program* means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under § 8.3(d).

*Certification* means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

*Certification application* means the application filed by an opioid treatment program for purposes of obtaining cer-

tification from SAMHSA, as described in § 8.11(b).

*Certified opioid treatment program* means an opioid treatment program that is the subject of a current, valid certification under § 8.11.

*Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

*Detoxification treatment* means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

*Federal opioid treatment standards* means the standards established by the Secretary in § 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

*For-cause inspection* means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

*Interim maintenance treatment* means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

*Long-term detoxification treatment* means detoxification treatment for a period more than 30 days but not in excess of 180 days.

*Maintenance treatment* means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

*Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

*Medical and rehabilitative services* means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

*Medication unit* means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

*Opiate addiction* is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

*Opioid agonist treatment medication* means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

*Opioid drug* means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

*Opioid treatment* means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services,

when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

*Opioid treatment program* or "OTP" means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

*Patient* means any individual who undergoes treatment in an opioid treatment program.

*Program sponsor* means the person named in the application for certification described in §8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

*Registered opioid treatment program* means an opioid treatment program that is registered under 21 U.S.C. 823(g).

*Short-term detoxification treatment* means detoxification treatment for a period not in excess of 30 days.

*State Authority* is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

*Treatment plan* means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.