

42 C.F.R. § 8.1

Scope.

(a) *Scope.* This subpart and subparts B through D of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under this subpart and subparts B through D, an applicant seeking to become an OTP must first obtain from the Secretary or, by delegation, from the Assistant Secretary for Mental Health and Substance Use, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the applicant obtaining accreditation from an Accreditation Body that has been approved by the Secretary. This subpart and subparts B through D also establish the procedures whereby an entity can apply to become an approved Accreditation Body, and the requirements and general standards for Accreditation Bodies to ensure that OTPs are consistently evaluated for compliance with the Secretary's standards for treatment of OUD with MOUD.

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