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## 42 C.F.R. § 8.11

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### Opioid Treatment Program certification.

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(a) *General.* (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards in § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

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