

for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

Subpart E [Reserved]

Subpart F—Authorization To Increase Patient Limit to 275 Patients

SOURCE: 81 FR 44738, July 8, 2016, unless otherwise noted.

§ 8.610 Which practitioners are eligible for a patient limit of 275?

The total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C. 823(g)(2)(B)(iii) is 275 if:

(a) The practitioner possesses a current waiver to treat up to 100 patients under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) and has maintained the waiver in accordance with applicable statutory requirements without interruption for at least one year since the practitioner's notification of intent (NOI) under section 303(g)(2)(B) to treat up to 100 patients was approved;

(b) The practitioner:

(1) Holds additional credentialing as defined in § 8.2; or

(2) Provides medication-assisted treatment (MAT) utilizing covered medications in a qualified practice setting as defined in § 8.615;

(c) The practitioner has not had his or her enrollment and billing privileges in the Medicare program revoked under § 424.535 of this title; and

(d) The practitioner has not been found to have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a).

§ 8.615 What constitutes a qualified practice setting?

A qualified practice setting is a practice setting that:

(a) Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;

(b) Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;

(c) Uses health information technology (health IT) systems such as