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

electronic health records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information;

(d) Is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law. PDMP means a statewide electronic database that collects designated data on substances dispensed in the State. For practitioners providing care in their capacity as employees or contractors of a Federal government agency, participation in a PDMP is required only when such participation is not restricted based on their State of licensure and is in accordance with Federal statutes and regulations;

(e) Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

§ 8.620 What is the process to request a patient limit of 275?

In order for a practitioner to receive approval for a patient limit of 275, a practitioner must meet all of the requirements specified in § 8.610 and submit a Request for Patient Limit Increase to SAMHSA that includes all of the following:

(a) Completed Request for Patient Limit Increase form;

(b) Statement certifying that the practitioner:

(1) Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with opioid use disorders;

(2) Will provide patients with necessary behavioral health services as defined in § 8.2 or through an established formal agreement with another entity to provide behavioral health services;

(3) Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule (45 CFR part 160 and 45 CFR part 164, subparts A and E) and 42 CFR part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;

(4) Will use patient data to inform the improvement of outcomes;

(5) Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from legitimate treatment use;

(6) Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency situation that would impact a patient's access to care as defined in § 8.2; and

(7) Will notify all patients above the 100 patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide MAT services using buprenorphine to them and make every effort to transfer patients to other addiction treatment;

(c) Any additional documentation to demonstrate compliance with § 8.610 as requested by SAMHSA.

§ 8.625 How will a Request for Patient Limit Increase be processed?

(a) Not later than 45 days after the date on which SAMHSA receives a practitioner's Request for Patient Limit Increase as described in § 8.620, or renewal Request for Patient Limit Increase as described in § 8.640, SAMHSA shall approve or deny the request.

(1) A practitioner's Request for Patient Limit Increase will be approved if the practitioner satisfies all applicable requirements under §§ 8.610 and 8.620. SAMHSA will thereafter notify the practitioner who requested the patient limit increase, and the Drug Enforcement Administration (DEA), that the practitioner has been approved to treat up to 275 patients using covered medications. A practitioner's approval to treat up to 275 patients under this section will extend for a term not to exceed 3 years.

(2) SAMHSA may deny a practitioner's Request for Patient Limit Increase if SAMHSA determines that:

(i) The Request for Patient Limit Increase is deficient in any respect; or

(ii) The practitioner has knowingly submitted false statements or made