

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA-162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA-163—Application for Becoming an Accreditation Body under § 8.3.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

(c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of

the accreditation body under the regulations in subpart A of this part; and

(d) The accreditation body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

§ 8.22 Definitions.

The following definitions apply to this subpart C.

(a) *Appellant* means:

(1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or

(2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

(b) *Respondent* means SAMHSA.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.