with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or ''take-home'' use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

[66 FR 4090, Jan. 17, 2001, as amended at 68 FR 27939, May 22, 2003; 77 FR 72761, Dec. 6, 2012]

§8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will

initiate procedures to revoke the facility's certification in accordance with §8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under §8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.