

to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

#### § 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

#### § 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application