
42 C.F.R. § 3.108

Correction of deficiencies, revocation, and voluntary relinquishment.

(a) *Process for correction of a deficiency and revocation—*(1) *Circumstances leading to revocation.* The Secretary may revoke his acceptance of an entity's certification (“revocation”) and delist the entity as a PSO if he determines—

(i) The PSO is not fulfilling the certifications made to the Secretary as required by § 3.102;

(ii) The PSO has not met the two contract requirement, as required by § 3.102(d)(1);

(iii) Based on a PSO's disclosures made pursuant to § 3.102(d)(2) , that the entity cannot fairly and accurately perform the patient safety activities of a PSO with a public finding to that effect; or

(iv) The PSO is not in compliance with any other provision of the Patient Safety Act or this part.

(2) *Notice of preliminary finding of deficiency and establishment of an opportunity for correction of a deficiency.* (i) Except as provided by paragraph (e) of this section, if the Secretary determines that a PSO is not in compliance with its obligations under the Patient Safety Act or this subpart, the Secretary must send a PSO written notice of the preliminary finding of deficiency. The notice must state the actions or inactions that encompass the deficiency finding, outline the evidence that the deficiency exists, specify the possible and/or required corrective actions that must be taken, and establish a date by which the deficiency must be corrected. The Secretary may specify in the notice the form of documentation required to demonstrate that the deficiency has been corrected.

(ii) The notice of a preliminary finding of deficiency is presumed received five days after it is sent, absent evidence of the actual receipt date. If a PSO does not submit evidence to the Secretary within 14 calendar days of actual or constructive receipt of such notice, whichever is longer, which demonstrates that the preliminary finding is factually incorrect, the preliminary finding will be the basis for a finding of deficiency.

(3) *Determination of correction of a deficiency.* (i) Unless the Secretary specifies another date, the Secretary must receive documentation to demonstrate that the PSO has corrected any deficiency cited in the preliminary finding of deficiency no later than five calendar days following the last day of the correction period that is specified by the Secretary in such notice.

(ii) In making a determination regarding the correction of any deficiency, the Secretary will consider the documentation submitted by the PSO, any assessments under § 3.110, recommendations of program staff, and any other information available regarding the PSO that the Secretary deems appropriate and relevant to the PSO's implementation of the terms of its certification.

(iii) After completing his review, the Secretary may make one of the following determinations:

(A) The action(s) taken by the PSO have corrected any deficiency, in which case the Secretary will withdraw the notice of deficiency and so notify the PSO;

(B) The PSO has acted in good faith to correct the deficiency, but the Secretary finds an additional period of time is necessary to achieve full compliance and/or the required corrective action specified in the notice of a preliminary finding of deficiency needs to be modified in light of the experience of the PSO in attempting to implement the corrective action, in which case the Secretary will extend the period for correction and/or modify the specific corrective action required; or

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