

publicly available list of entities whose certifications as PSOs have been accepted. The list will include contact information for each entity, a copy of all certification forms and disclosure statements submitted by each entity in accordance with paragraph (c)(3)(ii) of this section, the effective date of the PSO's listing, and information on whether a PSO has certified that it has met the two contract requirement. The list also will include a copy of the Secretary's findings regarding each disclosure statement submitted by an entity, information describing any related conditions that have been placed by the Secretary on the listing of an entity as a PSO, and other information that this Subpart states may be made public. AHRQ may maintain a PSO website (or a comparable future form of public notice) and may post the list on this website.

(e) *Three-year period of listing.* (1) The three-year period of listing of a PSO will automatically expire at midnight of the last day of this period, unless the listing had been revoked or relinquished earlier in accordance with §3.108 of this subpart, or if, prior to this automatic expiration, the PSO seeks a new three-year listing, in accordance with §3.102, and the Secretary accepts the PSO's certification for a new three-year listing, in accordance with §3.104(a).

(2) The Secretary plans to send a written notice of imminent expiration to a PSO at least 60 calendar days prior to the date on which its three-year period of listing expires if the Secretary has not yet received a certification for continued listing. The Secretary plans to indicate, on the AHRQ PSO website, the PSOs from whom certifications for continued listing have not been timely received.

(f) *Effective dates of Secretarial actions.* Unless otherwise stated, the effective date of each action by the Secretary pursuant to this subpart will be specified in the written notice of such action that is sent to the entity. When the Secretary sends a notice that addresses acceptance or revocation of an entity's certifications or voluntary relinquishment by an entity of its status as a PSO, the notice will specify the ef-

fective date and time of listing or delisting.

### §3.106 Security requirements.

(a) *Application.* A PSO must secure patient safety work product in conformance with the security requirements of paragraph (b) of this section. These requirements must be met at all times and at any location at which the PSO, its workforce members, or its contractors receive, access, or handle patient safety work product. Handling patient safety work product includes its processing, development, use, maintenance, storage, removal, disclosure, transmission and destruction.

(b) *Security framework.* A PSO must have written policies and procedures that address each of the considerations specified in this subsection. In addressing the framework that follows, the PSO may develop appropriate and scalable security standards, policies, and procedures that are suitable for the size and complexity of its organization.

(1) *Security management.* A PSO must address:

(i) Maintenance and effective implementation of written policies and procedures that conform to the requirements of this section to protect the confidentiality, integrity, and availability of the patient safety work product that is received, accessed, or handled; and to monitor and improve the effectiveness of such policies and procedures, and

(ii) Training of the PSO workforce and PSO contractors who receive, access, or handle patient safety work product regarding the requirements of the Patient Safety Act, this Part, and the PSO's policies and procedures regarding the confidentiality and security of patient safety work product.

(2) *Distinguishing patient safety work product.* A PSO must address:

(i) Maintenance of the security of patient safety work product, whether in electronic or other media, through either physical separation from non-patient safety work product, or if co-located with non-patient safety work product, by making patient safety work product distinguishable so that the appropriate form and level of security can be applied and maintained;

(ii) Protection of the media, whether in electronic, paper, or other media or format, that contain patient safety work product, limiting access to authorized users, and sanitizing and destroying such media before their disposal or release for reuse; and

(iii) Physical and environmental protection, to control and limit physical and virtual access to places and equipment where patient safety work product is received, accessed, or handled.

(3) *Security control and monitoring.* A PSO must address:

(i) Identification of those authorized to receive, access, or handle patient safety work product and an audit capacity to detect unlawful, unauthorized, or inappropriate receipt, access, or handling of patient safety work product, and

(ii) Methods to prevent unauthorized receipt, access, or handling of patient safety work product.

(4) *Security assessment.* A PSO must address:

(i) Periodic assessments of security risks and controls to establish if its controls are effective, to correct any deficiency identified, and to reduce or eliminate any vulnerabilities.

(ii) System and communications protection, to monitor, control, and protect PSO receipt, access, or handling of patient safety work product with particular attention to the transmission of patient safety work product to and from providers, other PSOs, contractors or any other responsible persons.

**§ 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.