
42 C.F.R. § 3.102

Process and requirements for initial and continued listing of PSOs.

(a) *Eligibility and process for initial and continued listing—(1) Submission of certification.* Any entity, except as specified in paragraph (a)(2) of this section, may request from the Secretary an initial or continued listing as a PSO by submitting a completed certification form that meets the requirements of this section, in accordance with § 3.112. An individual with authority to make commitments on behalf of the entity seeking listing will be required to submit contact information for the entity and:

- (i) Attest that the entity is not subject to any exclusion in paragraph (a)(2) of this section;
- (ii) Provide certifications that the entity meets each requirement for PSOs in paragraph (b) of this section;
- (iii) If the entity is a component of another organization, provide the additional certifications that the entity meets the requirements of paragraph (c)(1)(i) of this section;
- (iv) If the entity is a component of an excluded entity described in paragraph (a)(2)(ii), provide the additional certifications and information required by paragraph (c)(1)(ii) of this section;
- (v) Attest that the entity has disclosed if the Secretary has ever delisted this entity (under its current name or any other) or refused to list the entity or whether any of its officials or senior managers held comparable positions of responsibility in an entity that was denied listing or delisted and, if any of these circumstances apply, submit with its certifications and related disclosures, the name of the entity or entities that the Secretary declined to list or delisted;
- (vi) Attest that the PSO will promptly notify the Secretary during its period of listing if it can no longer comply with any of its attestations and the applicable requirements in §§ 3.102(b) and 3.102(c) or if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes; and
- (vii) Provide other information that the Secretary determines to be necessary to make the requested listing determination.

(2) *Exclusion of certain entities.* The following types of entities may not seek listing as a PSO:

- (i) A health insurance issuer; a unit or division of a health insurance issuer; or an entity that is owned, managed, or controlled by a health insurance issuer;
- (ii)
 - (A) An entity that accredits or licenses health care providers;
 - (B) An entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services;

(C) An agent of an entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; or

(D) An entity that operates a Federal, state, local or Tribal patient safety reporting system to which health care providers (other than members of the entity's workforce or health care providers holding privileges with the entity) are required to report information by law or regulation.

(iii) A component of an entity listed in paragraph (a)(2)(ii) may seek listing as a component PSO subject to the requirements and restrictions of paragraph (c)(1)(ii) of this section.

(3) *Submission of certification for continued listing.* To facilitate a timely Secretarial determination regarding acceptance of its certification for continued listing, a PSO must submit the required certification no later than 75 days before the expiration of a PSO's three-year period of listing.

(b) *Fifteen general PSO certification requirements.* The certifications submitted to the Secretary in accordance with paragraph (a)(1)(ii) of this section must conform to the following 15 requirements:

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