

PATIENT SAFETY ORGANIZATION: CERTIFICATION FOR INITIAL LISTING

Before completing this form, please review the requirements of the rule specified in 42 CFR Part 3, especially sections 3.102 and 3.106. The rule implements the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), which authorizes the creation of Patient Safety Organizations (PSOs). The Agency for Healthcare Research and Quality (AHRQ) of the Department of Health and Human Services (HHS) administers the provisions of the Patient Safety Act dealing with PSO operations. The rule and other PSO-related information are available on AHRQ's PSO Web site at www.pso.ahrq.gov.

An entity seeking initial listing by the HHS Secretary as a PSO must complete this form, which summarizes the 15 statutory requirements that all PSOs must certify they meet, the three additional statutory criteria that component organizations must meet, and other listing requirements specified in this rule.

The Secretary will notify the entity in writing of acceptance or non-acceptance of this certification. If this certification is accepted, the Secretary will list the PSO for three years beginning on a date and time specified in the PSO's notification of listing.

An entity is encouraged, but not required, to develop and post on a Web site a supplementary narrative that:

- 1) addresses how the entity will approach its mission and carry out required patient safety activities, and
- 2) outlines the expertise of its personnel (both employees and contractors) to carry out its mission.

Please submit this form to AHRQ's PSO Office via email, if possible, at PSO@ahrq.hhs.gov. To submit a hard copy, please send to: PSO Office, AHRQ, 540 Gaither Road, Rockville, MD 20850.

PART I: ENTITY CONTACT INFORMATION

Please complete the following information about the entity seeking listing as a PSO, which will be used for the "[Listed PSOs](http://www.pso.ahrq.gov/listing/psolist.htm)" section (<http://www.pso.ahrq.gov/listing/psolist.htm>) of the AHRQ PSO Web site.

If the entity seeking listing is a component of another (parent) organization, the name listed in Part I cannot be identical to that of the parent organization. However, a component of the XYZ organization could seek listing as the XYZ PSO. To determine whether an entity is a component, consult the definitions of component and parent organizations in section 3.20 of the rule.

Name of Entity Seeking Listing as a PSO		Entity Web Site	
Street Address	City	State	Zip Code
Mailing Address (if different than street address)	City	State	Zip Code

PART II: ATTESTATION REGARDING REGULATORY REQUIREMENTS

<p>A. Do you attest that the entity is not excluded from seeking listing by section 3.102(a)(2) of the rule?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>B. Is the entity a component of another organization?</p> <p>If the answer is “no”, skip to question D1.</p> <p>If the answer is “yes”, please provide contact information below for the parent organization as required by section 3.102(c)(1)(i) of the rule. If the component has more than one parent organization, attach an additional sheet to this certification form with the information on the additional parent organization(s); please prominently note the name of the entity seeking listing at the top of the additional sheet. To determine whether the component organization seeking listing has more than one parent organization, review the definitions of each of these terms in section 3.20 of the rule.</p> <p><i>Parent Organization Name:</i> _____</p> <p><i>Parent Organization Address:</i> _____</p> <p><i>Parent Organization Phone:</i> _____ <i>Fax:</i> _____</p> <p><i>Parent Organization Web Site:</i> _____</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C. Is the entity subject to the requirements of section 3.102(c)(1)(ii) of the rule (i.e., the parent organization is an excluded entity)?</p> <p>If the answer is “no”, please proceed to question D1. If the answer is “yes”, complete questions C1 – C6.</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C1. Have you attached a statement outlining the role and authority of the parent organization as required by section 3.102(c)(4)(i)(A)?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C2. Does the parent organization have policies and procedures in place that would require or induce providers to report patient safety work product (PSWP) to the component if listed as a PSO? [See the prohibition in section 3.102(c)(4)(i)(B).]</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C3. If listed as a PSO, will the component notify the Secretary within five calendar days if the parent organization adopts such policies or procedures that would require or induce providers to report PSWP to the component? [See section 3.102(c)(4)(i)(B).]</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C4. If listed as a PSO, will the component prominently post notification on its Web site, and publish in any promotional materials for dissemination to providers, a summary of the parent organization’s role and authority as required by section 3.102(c)(4)(i)(C)?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C5. If listed as a PSO, will the entity comply with the restrictions of section 3.102(c)(4)(ii)(A) that prohibits the sharing of staff with the parent organization?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>C6. If listed as a PSO, will the entity comply with the additional restrictions on contracting with the parent organization in section 3.102(c)(4)(ii)(B) of the rule?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>D1. Has the Secretary ever delisted this entity (under its current name or any other) or refused to list the entity?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>D2. Have any of this entity’s officials or senior managers held comparable positions of responsibility in an entity that was denied listing or delisted?</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO
<p>D3. Only if the answer to questions D1 or D2 is “yes”, please provide here the name of the entity or entities that the Secretary declined to list or delisted [see section 3.102(a)(1)(v)].</p>	

PART III: ATTESTATIONS REGARDING STATUTORY REQUIREMENTS FOR INITIAL CERTIFICATION

Attestations Regarding Patient Safety Activities

As specifically certified below, the entity seeking listing in Part I attests that it has policies and procedures in place to perform each of the eight statutorily-required Patient Safety Activities (items 1-8). Please review the definition of Patient Safety Activities in section 3.20 of the rule before completing these items.

Note that at the time a PSO seeks continued listing, it must certify that it has performed all eight patient safety activities.

1.	Does the entity have policies and procedures in place to improve patient safety and the quality of health care delivery?	<input type="checkbox"/> YES <input type="checkbox"/> NO
2.	Does the entity have policies and procedures in place for the collection and analysis of patient safety work product (PSWP)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
3.	Does the entity have policies and procedures in place to develop and disseminate information with respect to improving patient safety, such as recommendations, protocols, and best practices?	<input type="checkbox"/> YES <input type="checkbox"/> NO
4.	Does the entity have policies and procedures in place to utilize PSWP to encourage a culture of safety, to provide feedback, and to provide assistance to effectively minimize patient risk?	<input type="checkbox"/> YES <input type="checkbox"/> NO
5.	Does the entity have policies and procedures in place to preserve confidentiality of PSWP in conformity with the rule and the authorizing statute?	<input type="checkbox"/> YES <input type="checkbox"/> NO
6.	Does the entity have policies and procedures in place to protect PSWP in conformity with the rule and the authorizing statute?	<input type="checkbox"/> YES <input type="checkbox"/> NO
7.	Does the entity have policies and procedures in place to assure the utilization of appropriately qualified staff?	<input type="checkbox"/> YES <input type="checkbox"/> NO
8.	Does the entity have policies and procedures in place to perform the collection, management, and analytic activities related to the operation of a patient safety evaluation system (PSES), including the provision of feedback to participants in a PSES?	<input type="checkbox"/> YES <input type="checkbox"/> NO

Attestations Regarding Patient Safety Criteria

As specifically certified below, the entity seeking listing in Part I attests that, if listed, it will comply throughout its period of listing with each of the statutorily-required criteria for listing (items 9-15). Please review the criteria, which are incorporated in section 3.102(b)(2) of the rule, before completing these items.

9.	Will improvement of patient safety and the quality of health care delivery be both (a) the entity's mission and (b) the entity's primary activity? A "yes" answer attests that both (a) and (b) will be met.	<input type="checkbox"/> YES <input type="checkbox"/> NO
10.	Will the entity's employees or contractors both (a) be appropriately qualified and (b) include licensed or certified medical professionals?	<input type="checkbox"/> YES <input type="checkbox"/> NO
11.	Will the entity meet the requirement to enter at least two bona fide contracts within 24 months of its initial listing (and meet that test in every subsequent 24-month period)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
12.	Will the entity comply with the prohibition that it may not be a health insurance insurer or a health insurance insurer component?	<input type="checkbox"/> YES <input type="checkbox"/> NO
13.	Will the entity meet the requirement to fully disclose to the Secretary relationships with contracting providers?	<input type="checkbox"/> YES <input type="checkbox"/> NO
14.	Will the entity collect PSWP in a standardized manner that permits valid comparisons of similar cases? Note: The Secretary is providing guidance on common definitions and reporting formats, known as Common Formats, which is available at www.pso.ahrq.gov .	<input type="checkbox"/> YES <input type="checkbox"/> NO
15.	Will the entity utilize PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk?	<input type="checkbox"/> YES <input type="checkbox"/> NO

ONLY ANSWER QUESTIONS 16-18 IF YOUR ENTITY IS A COMPONENT ORGANIZATION

Consult section 3.102(c) of the rule before completing questions 16-18. To determine whether a component organization has more than one parent organization, consult the definition of both terms in section 3.20 of the rule.

16.	Will the component entity maintain PSWP separately from the rest of the parent organization(s) and establish appropriate security measures to maintain the confidentiality of PSWP?	<input type="checkbox"/> YES <input type="checkbox"/> NO
17.	Will the component entity require that members of its workforce and any other contractor staff not make unauthorized disclosures of PSWP to the rest of the parent organization(s)?	<input type="checkbox"/> YES <input type="checkbox"/> NO
18.	Will the component entity ensure that the pursuit of its mission will not create a conflict of interest with the rest of its parent organization(s)?	<input type="checkbox"/> YES <input type="checkbox"/> NO

Please note that if the answer is "no" for any of the questions (1-18), additional clarification may be sought before the Secretary makes a determination regarding initial listing.

PART IV: CERTIFICATION OF ATTESTATIONS

I am authorized to complete this form on behalf of the entity seeking listing as a PSO. The statements on this form, and any submitted attachments or supplements to it, are made in good faith and are true, complete, and correct to the best of my knowledge and belief. I understand that a knowing and willful false statement on this form, attachments or supplements to it, can be punished by fine or imprisonment or both (United States Code, Title 18, Section 1001). I also understand that the rule requires that if any change takes place that would render any attestation inaccurate or incomplete, or if there is a change in the contact information provided, the entity seeking listing must promptly notify the Secretary of any such change by contacting AHRQ's PSO Office via email at PSO@ahrq.hhs.gov or toll free at (866) 403-3697 or (866) 438-7231 (TTY).

Authorized Official Signature: _____

Authorized Official Printed Name: _____

Authorized Official Title: _____

Date: _____

Telephone: _____

Fax: _____

E-mail: _____

If the person completing this form will not be the primary point of contact, please provide the point of contact information below:

Point of Contact: _____

Point of Contact Telephone: _____

Point of Contact E-mail: _____

This completed form is considered public information.

Burden Statement

Public reporting burden for the collection of information is estimated to average 30 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.