

# Patient Safety Organization: Certification for Initial Listing

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), and its implementing regulations in 42 CFR Part 3 (Patient Safety Rule), authorize 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 and Patient Safety Rule dealing with PSO operations. Information related to PSOs is available on AHRQ's PSO Web site at [www.pso.ahrq.gov](http://www.pso.ahrq.gov).

Please review the Patient Safety Act, Patient Safety Rule, and the Guidance before completing this form. This form sets forth the requirements that all PSOs, component organizations, and FDA-Regulated Reporting Entities (or organizationally related entities) must certify they meet and understand to become a PSO. An entity seeking initial listing by the Secretary as a PSO must complete this form.

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

Note: In completing this form, you may be asked to provide additional information in an attachment. When doing so, please be sure to note the entity name prominently at the top of the attachment.

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" section of the AHRQ PSO Web site ( <a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a> ). If the entity seeking listing is a component of another (parent) organization, the name listed below 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 Patient Safety Rule.			
Name of the PSO			
PSO Web Site (if the Web site will be operational upon listing)			
Street Address	City	State	Zip Code
Mailing Address (if different than street address)	City	State	Zip Code
PSO Phone	PSO Fax		



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<b>Part II: Attestations Regarding Regulatory Requirements</b>		
A.	Do you attest that the entity is not excluded from seeking listing by section 3.102(a)(2) of the rule?	<input type="checkbox"/> Yes <input type="checkbox"/> No
B1.	Is the entity seeking listing a component of another organization according to the definition in section 3.20 of the Patient Safety Rule? <b><i>If the answer is "no," skip to question D1.</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
B2.	Is the entity seeking listing a separate legal entity from the parent organization?	<input type="checkbox"/> Yes <input type="checkbox"/> No
B3.	Is the parent organization of the entity seeking listing a legal entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C1.	Is the entity subject to the requirements of section 3.102(c)(1)(ii) of the Patient Safety Rule (i.e., the parent organization is an excluded entity)? <b><i>If the answer is "no," please proceed to question D1. If the answer is "yes," complete questions C2-C7.</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
C2.	Have you attached a statement outlining the role and authority of the parent organization as required by section 3.102(c)(4)(i)(A)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C3.	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).]	<input type="checkbox"/> Yes <input type="checkbox"/> No
C4.	If listed as a PSO, will the component notify the Secretary within 5 calendar days if the parent organization adopts such policies or procedures as described in C3 that would require or induce providers to report PSWP to the component? [See section 3.102(c)(4)(i)(B).]	<input type="checkbox"/> Yes <input type="checkbox"/> No
C5.	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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C6.	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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
C7.	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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
D1.	Has the Secretary ever delisted this entity (under its current name or any other) or refused to list the entity? In responding to this question, please note that delisting includes expiration of listing, revocation of a listing for cause, and voluntary relinquishment of a listing by a PSO. If the answer to question D1 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)]. Delisted PSO name _____	<input type="checkbox"/> Yes <input type="checkbox"/> No
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?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<b>Part III: Attestations Regarding Statutory Requirements For Initial Certification</b>		
<b>Attestations Regarding Patient Safety Activities</b>		
At the time this form is submitted, the entity seeking listing as a PSO attests that its policies and procedures are complete and ready to guide the PSO's workforce and its contractors in the performance of 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 Patient Safety Rule before completing these items.		
<b>Note that at the time a PSO seeks continued listing, it must certify that it has performed all eight patient safety activities.</b>		
1.	Does the entity have policies and procedures 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 for the collection and analysis of PSWP?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Does the entity have policies and procedures 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 to use 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 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 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
<b>Attestations Regarding Patient Safety Criteria</b>		
As specifically certified below, the entity seeking listing as a PSO 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 Patient Safety Rule, before completing these items.		
9.	Will the conduct of activities to improve 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 workforce both (a) be appropriately qualified and (b) include licensed or certified medical professionals? A "yes" answer attests that both (a) and (b) will be met.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Will the entity meet the requirement to have at least two bona fide contracts within 24 months of its date of initial listing (and meet that test in every subsequent 24-month period)?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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12.	Will the entity comply with the prohibition that it may not be a health insurance issuer or a component of a health insurance issuer?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13.	Will the entity meet the requirement to fully disclose to the Secretary relationships with contracted 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 among similar providers? Note: The Secretary has provided common definitions and reporting formats, known as Common Formats, which are available at <a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a> .	<input type="checkbox"/> Yes	<input type="checkbox"/> No
15.	Will the entity use 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

**Attestations for Component Organizations**

If the entity seeking listing as a PSO is a component organization, please complete the information below as required by section 3.102(c)(1)(i). If not, skip to Part IV.

Contact information for all of the entity's parent organization(s) must be provided below. 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 Patient Safety Rule. If necessary, please provide this information in an attachment to this certification form.

Parent Organization Name

Parent Organization Address

Parent Organization Phone

Parent Organization Fax

Parent Organization Web site

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 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

<b>Part IV: Supplemental Attestations Regarding Food And Drug Administration (FDA) Reporting Obligations Of PSOs</b>		
<p>HHS Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 clarifies the obligations that an entity must meet to be and remain listed as a PSO when the entity or PSO is an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity. Before completing Part IV, please review this Guidance document, which is available on AHRQ's PSO Web site at <a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a> under "Legislation, Regulations, and Guidance."</p>		
1.	<p>Is the entity an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity?</p> <p><b><i>If the answer to question #1 is "no," proceed to Part V.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	<p>Is the entity seeking listing as a component PSO?</p> <p><b><i>If the answer to question #2 is no, please proceed to Part V. If the answer to question #2 is yes, please answer questions #3 and #4.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	<p>Has the entity reviewed the Guidance regarding the obligations of a PSO that is an FDA-regulated reporting entity, or is organizationally related to such an entity, and concluded that it can and will meet its mandatory FDA-reporting requirements (including (a) disclosing relevant PSWP held by the component PSO to the FDA-regulated reporting entity and to the FDA, and providing FDA with access to such PSWP (held at the PSO); and (b) having the component PSO disclose relevant PSWP to the FDA-regulated reporting entity of which it is a part, to ensure that such entity meets its FDA-reporting requirements) during its period of listing as a PSO?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	<p>Does the entity understand that failure of a component PSO to comply with its FDA-reporting requirements (including the failure to (a) disclose relevant PSWP held by the component PSO to the FDA-regulated reporting entity and to the FDA, and provide FDA with access to such PSWP (held by the PSO); and (b) have the component PSO disclose relevant PSWP to the FDA-regulated reporting entity of which it is part, to ensure that such entity meets its FDA-reporting requirements) will constitute a conflict of interest and will be a basis for delisting a component PSO?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

### Part V: Certification of Attestations

I am legally 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, upon listing as a PSO, the Patient Safety Rule requires that if there are any changes in the accuracy of the information provided or if there is a change in the contact information provided, the entity seeking listing as PSO must promptly notify AHRQ by contacting AHRQ's PSO Office via email at [PSO@ahrq.hhs.gov](mailto:PSO@ahrq.hhs.gov) or TTY (toll free) at 866-403-3697 or 866-438-7231.

Authorized Official Printed Name

Authorized Official Title

Authorized Official Organization (if different from PSO)

Authorized Official Signature

Date:

Authorized Official Phone

Authorized Official Email

Authorized Official Fax

If the authorized official is not the primary point of contact for the PSO, please provide information for the point of contact below:

Point of Contact Name

Point of Contact Title

Point of Contact Organization

Point of Contact Phone

Point of Contact Email

Point of Contact Fax

**This completed form is considered public information.**

#### **Burden Statement**

Public reporting burden for the collection of information is estimated to average 18 hours 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.