

# Patient Safety Organization: Certification for Continued Listing

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), and its implementing regulations at 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 continued 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, 5600 Fishers Lane, Rockville, MD 20857.

**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 PSO name and number prominently at the top of the attachment.**

Part I: PSO Contact Information			
Please review the following information about the PSO, which is posted on the "Listed PSOs" section of the AHRQ PSO Web site ( <a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a> ), and indicate below only (a) the PSO's name and number, and (b) any changes that are necessary.			
AHRQ Assigned PSO Number	PSO Name		
PSO Web Site			
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.	<p>Are all of the attestations and the information submitted, in support of your current certification for listing, still accurate with respect to the PSO, and if applicable, its parent organization(s)?</p> <p><b><i>If the answer is “yes,” the PSO is attesting that there have been no changes and that the PSO is still eligible for listing. Please consult section 3.102(a)(2) of the Patient Safety Rule.</i></b></p> <p><b><i>If the answer is “no,” please explain the PSO’s changes in an attachment to this certification form.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
B1.	<p>Is the PSO a component of another organization?</p> <p><b><i>If the answer is “no,” please proceed to D1.</i></b></p> <p><b><i>If the answer is “yes,” complete questions B2-B3 before proceeding to question C1.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
B2.	<p>Is the PSO seeking continued listing a separate legal entity from the parent organization?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
B3.	<p>Is the parent organization of the PSO a legal entity?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
C1.	<p>Is the component PSO 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)?</p> <p><b><i>If the answer is “no,” please proceed to D1.</i></b></p> <p><b><i>If the answer is “yes,” please complete questions C2-C3 before proceeding to D1.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
C2.	<p>Has the component PSO complied with requirements of section 3.102(c)(4) of the Patient Safety Rule during its current period of listing?</p> <p><b><i>If the answer is “no,” please provide additional details in an attachment to this certification form.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
C3.	<p>If the Secretary approves this request for continued listing, will the component PSO comply with the requirements of section 3.102(c)(4) during its period of continued listing?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
D1.	<p>Since the time your PSO last attested for initial or continued listing, has the PSO added any personnel who were previously associated with a PSO that was previously delisted by the Secretary?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

<b>Part III: Attestations Regarding Statutory Requirements</b>		
<b>Attestations Regarding Patient Safety Activities</b>		
As specifically certified below, the PSO attests that it is (a) currently performing, and (b) will continue to perform in accordance with its policies and procedures, each of the statutorily-required patient safety activities (items 1-8) throughout the period of continued listing. A “yes” answer means that the PSO is attesting to both (a) and (b). Please note that if the answer is “no” for any of the items below, additional clarification may be sought before the Secretary makes a determination regarding continued listing.		
<b>Is the PSO performing, and will the PSO continue to perform, the following activities?</b>		
1.	Undertaking actions to improve patient safety and the quality of health care delivery?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Collecting and analyzing patient safety work product (PSWP)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Developing and disseminating information with respect to improving patient safety such as recommendations, protocols, and best practices?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Using PSWP to encourage a culture of safety, to provide feedback and provide assistance to effectively minimize patient risk?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Implementing and maintaining procedures to preserve confidentiality of PSWP in conformity with the Patient Safety Rule and the authorizing statute?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Implementing and maintaining security measures to protect PSWP in conformity with the Patient Safety Rule and the authorizing statute?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	Using appropriately qualified staff?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Performing 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 PSO attests that it is (a) currently performing, and (b) will continue to perform, each of the statutorily-required patient safety criteria for PSOs (items 9-15) throughout the period of continued listing. A “yes” answer means that you are attesting to both (a) and (b).		
9.	Conducting activities to improve patient safety and the quality of health care delivery that are both (a) the PSO’s mission and (b) the PSO’s primary activity? A “yes” answer attests that both conditions are met.	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	Using workforce members who (a) are appropriately qualified and (b) who include licensed or certified medical professionals? A “yes” answer attests that both conditions are met.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Meeting the requirement to have at least two bona fide contracts with providers within each of the required 24-month periods following the date of initial listing?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	Complying with the prohibition that it is not a health insurance issuer or a component of a health insurance issuer?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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13.	Fully disclosing to the Secretary relationships with contracted providers, as required by section 3.102(d)(2) of the Patient Safety Rule?	<input type="checkbox"/> Yes <input type="checkbox"/> No
14A.	Using the Common Formats, as published by AHRQ and available at <a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a> , for the collection of PSWP? <b><i>If the answer is "no," please proceed to question 14B.</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
14B.	Using another system to collect PSWP from providers in a standardized manner that permits valid comparisons among similar providers? <b><i>If the answer is "yes," please provide additional details in an attachment to this certification form.</i></b> <b><i>If the answer is "no," please explain in an attachment to this certification form why it is not practical or appropriate to comply with the options described in question 14A or 14B.</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
15.	Using PSWP for the purpose of providing feedback and assistance to providers, to effectively minimize patient risk?	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Attestations for Component Organizations**

If the PSO is seeking continued listing as a component organization, please complete the information below as required by section 3.102(c)(1)(i) of the Patient Safety Rule. If not, skip to Part IV. Contact information for parent organization(s) must be provided below. 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

As specifically certified below, the PSO attests that it is (a) currently complying with, and (b) will continue to comply with, each of the additional statutory requirements below throughout the period of continued listing.

16.	Maintaining PSWP separately from the PSO's parent organization(s) and has established appropriate security measures to maintain the confidentiality of PSWP?	<input type="checkbox"/> Yes <input type="checkbox"/> No
17.	Requiring 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.	Ensuring that the pursuit of its mission is not creating 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 a PSO must meet to remain listed when the PSO is an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity. Before completing this attestation form, 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 PSO an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity?</p> <p><b><i>If the answer is "no," proceed to Part V.</i></b></p> <p><b><i>If the answer is "yes," please complete question 2.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	<p>Is the PSO seeking continued listing a component PSO?</p> <p><b><i>If the answer is "no," please proceed to Part V.</i></b></p> <p><b><i>If the answer is "yes," please complete questions 3 and 4 before proceeding to Part V.</i></b></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	<p>Has the PSO 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 PSO 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 continued 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 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 continued listing as a 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 be the primary point of contact for the PSO, please provide the 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 8 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, 5600 Fishers Lane, Rockville, MD 20857.