Form Approved
OMB No. 0935-0143
Exp. Date ??/??/????

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), 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 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.

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 e-mail, at 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 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 (www.pso.ahrq.gov), and indicate below **only** (a) the PSO's name and number, and (b) any changes that are necessary.

PSO Name and Number	**PSO Web Site**		
Street Address	**City**	**State**	**Zip Code**
PSO Phone	**PSO Fax**		
Mailing Address (if different than street address)	**City**	**State**	**Zip Code**

PART II: ATTESTATIONS REGARDING REGULATORY REQUIREMENTS		
A.	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)? 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. If the answer is “no”, please explain the PSO’s changes in an attachment to this certification form.	___ Yes ___ No
B1.	Is the PSO a component of another organization? *If the answer is “no”, please proceed to D1.* *If the answer is "yes", complete questions B2-B3 before proceeding to question C1.*	___ Yes ___ No
B2.	Is the PSO seeking continued listing a separate legal entity from the parent organization?	___ Yes ___ No
B3.	Is the parent organization of the PSO a legal entity?	_ Yes _ No
C1.	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)? *If the answer is "no", please proceed to D1.* *If the answer is "yes", please complete questions C2-C3 before proceeding to D1.*	___ Yes ___ No
C2.	Has the component PSO complied with requirements of section 3.102(c)(4) of the Patient Safety Rule during its current period of listing? *If the answer is “no”, please provide additional details in an attachment to this certification form*.	___ Yes ___ No
C3.	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	___ Yes ___ No

	continued listing?	
D1.	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?	___ Yes ___ No

PART III: ATTESTATIONS REGARDING STATUTORY REQUIREMENTS

Attestations Regarding Patient Safety Activities

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.

Is the PSO performing, and will the PSO continue to perform, the following activities?

1.	Undertaking actions to improve patient safety and the quality of health care delivery?	___ Yes ___ No
2.	Collecting and analyzing patient safety work product (PSWP)?	___ Yes ___ No
3.	Developing and disseminating information with respect to improving patient safety such as recommendations, protocols, and best practices?	___ Yes ___ No
4.	Using PSWP to encourage a culture of safety, to provide feedback and provide assistance to effectively minimize patient risk?	___ Yes ___ No
5.	Implementing and maintaining procedures to preserve confidentiality of PSWP in conformity with the Patient Safety Rule and the authorizing statute?	___ Yes ___ No
6.	Implementing and maintaining security measures to protect PSWP in	___ Yes ___ No

	conformity with the Patient Safety Rule and the authorizing statute?	
7.	Using appropriately qualified staff?	___ Yes ___ 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?	___ Yes ___ No

Attestations Regarding Patient Safety Criteria

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.	___ Yes ___ 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.	___ Yes ___ 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?	___ Yes ___ No
12.	Complying with the prohibition that it is not a health insurance issuer or a component of a health insurance issuer?	___ Yes ___ No
13.	Fully disclosing to the Secretary relationships with contracted providers, as required by section 3.102(d)(2) of the Patient Safety Rule?	___ Yes ___ No
14A.	Using the Common Formats, as published by AHRQ, for the collection of PSWP which are available at www.pso.ahrq.gov? *If the answer is "no", please proceed to question 14B*.	___ Yes ___ No
14B.	Using another system to collect PSWP from providers in a standardized manner that permits valid comparisons among similar providers? *If the answer is “yes,” please provide additional details in an attachment to this certification form.* *If the answer is “no”, please explain why it is not practical or appropriate to comply with the options described in question 14A or 14B in an attachment to this certification form.*	___ Yes ___ No

15.	Using PSWP for the purpose of providing feedback and assistance to providers to effectively minimize patient risk?	___ Yes ___ 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?	___ Yes ___ 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)?	___ Yes ___ No
18.	Ensuring that the pursuit of its mission is not creating a conflict of interest with the rest of its parent organization(s)?	___ Yes ___ No

PART IV: SUPPLEMENTAL ATTESTATIONS REGARDING FOOD AND DRUG ADMINISTRATION (FDA) REPORTING OBLIGATIONS OF PSOs

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 www.pso.ahrq.gov under “Legislation, Regulations and Guidance.”

1.	Is the PSO an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity? *If the answer is “no”, proceed to Part V.* *If the answer is “yes”, please complete question 2.*	___ Yes ___ No
2.	Is the PSO seeking continued listing a component PSO? *If the answer is “no”, please proceed to Part V.* *If the answer is “yes”, please complete questions 3 and 4 before proceeding to Part V.*	___ Yes ___ No
3.	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 in order to ensure that such entity meets its FDA-reporting requirements) during its period of listing as a PSO?	___ Yes ___ No
4.	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 in order 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?	___ Yes ___ 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 e-mail at PSO@ahrq.hhs.gov or toll free at (866) 403-3697 or (866) 438-7231 (TTY).

Authorized Official Printed Name:

Authorized Official Title:

Authorized Official Organization (if different from PSO):

Authorized Official Signature:

Date:

Authorized Official Phone:

Authorized Official E-mail:

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:

Name:

Title:

Organization:

Phone:

E-mail:

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, 540 Gaither Road, Room #5036, Rockville, MD 20850.