Form Approved OMB No. ?
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, the Patient Safety Rule, and the Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (Guidance) before completing this form. This form sets forth the requirements that all PSOs must certify they meet, the three additional criteria that component organizations must meet, and other information that FDA-Regulated Reporting Entities, or those organizationally related to such entities, must certify they meet and/or understand. An entity seeking continued listing by the HHS 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.

PART I: PSO CONTACT INFORMATION

Please complete the following information about your PSO, which is posted on the "Listed PSOs" section of the AHRQ PSO Web site (http://www.pso.ahrq.gov/listing/psolist.htm).

PSO Name	PSO Web site		
Street Address	City	State	Zip Code
PSO Telephone	PSO Fax		
Mailing Address (if different from street address)	City	State	Zip Code

PART II: ATTESTATIONS REGARDING REGULATORY REQUIREMENTS

A.	Are all of the attestations and information you 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”, this means that you also attest that there have been no changes in the activities of the PSO that would make it ineligible for continued listing. Please consult section 3.102(a)(2) of the Patient Safety Rule for activities that make an entity ineligible for listing. If the answer is “no”, please explain your changes in an additional sheet attached to this certification form with the PSO name prominently noted at the top.	___ Yes	___ No
B1.	Is the PSO a component of another organization? *If the answer is "no", proceed to Part III.* *If the answer is "yes", complete questions B2-B3 before proceeding to question C.*	___ 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
C.	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 Part III.* *If the answer is "yes", please complete questions C1-C2 before proceeding to Part III.*	___ Yes	___ No
C1.	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 details here.	___ Yes	___ No
C2.	If the HHS Secretary approves this request for continued listing, will the component PSO comply with the requirements of section 3.104(c)(4) during its period of continued listing?	___ Yes	___ No

PART III: ATTESTATIONS REGARDING STATUTORY REQUIREMENTS

Attestations Regarding Patient Safety Activities

As specifically certified below, the PSO listed in Part I attests that it is (a) currently performing, and (b) will continue to perform, 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 questions (1-18), additional clarification may be sought before the HHS 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.	Utilizing PSWP to encourage a culture of safety, to provide feedback, and to 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 conformity with the Patient Safety Rule and the authorizing statute?	___ Yes ___ No
7.	Using appropriately qualified staff to improve patient safety and the quality of health care delivery?	___ 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 listed in Part I 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).

	Is the PSO complying with, and will the PSO continue to comply with, the following criteria?	
9.	Making the improvement of patient safety and the quality of health care delivery (a) the PSO's mission and (b) the PSO's primary activity? A "yes" answer attests that both conditions are met.	___ Yes ___ No
10.	Employing staff (employees or contractors) who are both (a) appropriately qualified and (b) include licensed or certified medical professionals?	___ Yes ___ No
11.	Meeting the requirement to enter at least two bona fide contracts within each of the required 24-month periods following initial listing?	___ Yes ___ No
12.	Complying with the prohibition that it may not be a health insurance issuer or a health insurance issuer component?	___ Yes ___ No
13.	Fully disclosing to the HHS Secretary relationships with contracting providers?	___ Yes ___ No
14A.	Using the HHS Secretary’s published Common Formats, which are available at www.pso.ahrq.gov, for the collection of PSWP? *If the answer is "yes", proceed to question 14B.* *If the answer is "no", proceed to question 14C.*	___ Yes ___ No
14B.	Deviating at all from the Common Formats, including any deviations from the technical specifications? *If the answer is “yes”, please provide additional detail in an attached statement and then proceed to question 15.* *If the answer is “no”, proceed to question 15.*	___ Yes ___ No
14C.	Using an alternate system of formats and definitions in its collection of PSWP that permits valid comparisons among similar providers? *If the answer is “yes”, proceed to question 15.* *If the answer is “no”, proceed to questions 14D – 14E.*	___ Yes ___ No
14D.	Attesting that it is not practical or appropriate to comply with the options described in questions 14A or 14C. *If the answer is “yes”, attach a separate sheet with a clear explanation of why it is not practical or appropriate for the PSO to comply with those options.*	___ Yes ___ No

14E.	If the answer to 14D is "yes", is the required explanatory statement attached to this form?	___ Yes ___ No
15.	Using PSWP to provide feedback and help to providers in order to minimize patient risk?	___ Yes ___ No

Attestations for Component Organizations

If your 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. Please be sure to include the contact information for all of the parent organization(s). If necessary, attach an additional sheet to this certification for with the PSO name prominently noted at the top.

Parent Organization Name	
Parent Organization Address	
Parent Organization Phone	Parent Organization Fax
Parent Organization Web site	

As specifically certified below, the PSO listed in Part I attests that it is (a) currently complying with, and (b) will continue to comply with, each of the additional statutory requirements for component PSOs (items 16-18) throughout the period of continued listing.

Is the PSO complying with, and will the PSO continue to comply with, the following requirements?

16.	Maintaining PSWP separately from the rest of the 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 will not create 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

On December 30, 2010, HHS issued Guidance that clarifies the obligations that an entity must meet to be listed and that a PSO must meet to remain listed as a PSO when the entity or PSO is an FDA-regulated reporting entity, i.e., it has mandatory FDA-reporting obligations under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. and its implementing regulations, or is organizationally related to an FDA-regulated reporting entity. Before completing this attestation form, please review the Guidance document. It 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?	___ Yes ___ No

If the answer is "no", proceed to Part V

If the answer is "yes", please complete question 2.

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

Authorized Official Printed Name

Authorized Official PSO Title

Authorized Official Organization (if different from PSO)

Authorized Official Signature

Date

Authorized Official Phone | Authorized Official Fax

Authorized Official Email

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

Point of Contact Name

Point of Contact Title | Point of Contact Organization

Point of Contact Phone | Point of Contact Email

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.