Form Approved
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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.

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 understand. An entity seeking initial 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: 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 (http://www.pso.ahrq.gov/listing/psolist.htm). 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 Patient Safety Rule.

Name of the Proposed PSO	Proposed PSO Web site		
Street Address	City	State	Zip Code
Phone	Fax		
Mailing Address (if different from street address)	City	State	Zip Code

PART II: ATTESTATIONS REGARDING REGULATORY REQUIREMENTS

A.	Do you attest that the entity is not excluded from seeking listing by section 3.102(a)(2) of the Patient Safety Rule?	___ Yes ___ No
B1.	Is the entity seeking listing a component of another organization? *If the answer is "no", skip to question D1.*	___ Yes ___ No
B2.	Is the entity seeking listing a separate legal entity from the parent organization?	___ Yes ___ No
B3.	Is the parent organization of the entity seeking listing a legal entity?	___ Yes ___ No
C.	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)? *If the answer is "no", please proceed to question D1. If the answer is "yes", complete questions C1-C6.*	___ Yes ___ No
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)?	___ Yes ___ No
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).]	___ Yes ___ No
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).]	___ Yes ___ No
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)?	___ Yes ___ No
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?	___ Yes ___ No
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?	___ Yes ___ No
D1.	Has the Secretary ever delisted this entity (under its current name or any other) or refused to list the entity?	___ Yes ___ 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?	___ Yes ___ No
D3.	Only if the answer to questions D1 or D2 is "yes", please provide the name of the entity or entities that the Secretary declined to list or delisted [see section 3.102(a)(1)(v)]. _____	

PART III: ATTESTATIONS REGARDING STATUTORY REQUIREMENTS FOR INITIAL CERTIFICATION

Attestations Regarding Patient Safety Activities

As specifically certified below, the entity seeking listing as a PSO 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 Patient Safety 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?	___ Yes	___ No
2.	Does the entity have policies and procedures in place for the collection and analysis of PSWP?	___ Yes	___ 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?	___ Yes	___ 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?	___ Yes	___ 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?	___ Yes	___ No
6.	Does the entity have policies and procedures in place to protect PSWP in conformity with the rule and the authorizing statute?	___ Yes	___ No
7.	Does the entity have policies and procedures in place to assure the utilization of appropriately qualified staff?	___ Yes	___ 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?	___ Yes	___ 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 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.	___ Yes	___ No
10.	Will the entity's employees or contractors 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.	___ Yes	___ No
11.	Will the entity meet the requirement to enter 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)?	___ Yes	___ No
12.	Will the entity comply with the prohibition that it may not be a health insurance issuer or a health insurance issuer component?	___ Yes	___ No
13.	Will the entity meet the requirement to fully disclose to the Secretary relationships with contracting providers?	___ Yes	___ No
14.	Will the entity collect PSWP in a standardized manner that permits valid comparisons of similar cases? Note: The HHS Secretary has provided common definitions and reporting formats, known as Common Formats., which are available at www.pso.ahrq.gov.	___ Yes	___ No
15.	Will the entity utilize PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk?	___ Yes	___ No

Attestations for Component Organizations

If the entity seeking listing as a PSO is a component organization, please complete the information below. If not, skip to Part IV. Consult section 3.102(c) of the Patient Safety Rule before completing this section. Please provide contact information below for the parent organization as required by section 3.102(c)(1)(i) of the Patient Safety 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 Patient Safety Rule.

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?	___ Yes	___ 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)?	___ Yes	___ 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)?	___ 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 entity an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity? *If the answer to question #1 is "no", proceed to Part V.*	___ Yes	___ No
2.	Is the entity seeking listing as a component PSO? *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.*	___ Yes	___ No
3.	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 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 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 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 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 listing as a PSO must promptly notify AHRQ 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 Printed Name
Authorized Official Title
Authorized Official Organization (if different from PSO)

Authorized Official Signature
Date
Authorized Official Phone
Authorized Official Fax
Authorized Official Email
If the authorized official 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 Fax
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 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.