CLEAN VERSION (09-26-2024)

Form Approved
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PATIENT SAFETY ORGANIZATION:

CERTIFICATION FOR CONTINUED LISTING

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) 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 website at www.pso.ahrq.gov.

This form sets forth the requirements that all PSOs seeking continued listing must certify they meet to maintain their listing as a PSO for a new three-year period of listing. Please review the Patient Safety Act, Patient Safety Rule, and all HHS Guidance before making the required attestations below. All references to "section" followed by a citation that begins with the number 3 within this form (e.g., "section 3.102") refer to sections of the Patient Safety Final Rule (73 F.R. 70732), which is codified in Title 42, Part 3 of the CFR. All references to Secretary within this form refer to the Secretary of HHS.

A PSO seeking continued listing must complete this form and submit it to AHRQ's PSO Office via email, at pso@ahrq.hhs.gov. To submit a hard copy, please send to: PSO Office, AHRQ, 5600 Fishers Lane, MS 06N100B, 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's name and number prominently at the top of the attachment.***

PART I: PSO CONTACT INFORMATION

PSO Number	**PSO Name**

PSO Website Address (Complete only if the PSO has an address that links to a PSO-specific website or web page)

Is the PSO a legal entity?	**___ Yes ___ No**
Does the PSO have an alternate legal name? *If the answer to this question is "Yes", please provide the name on the line below*	**___ Yes ___ No**

Physical Address	**City**	**State**	**Zip Code**
Mailing Address (if different from physical address)	**City**	**State**	**Zip Code**
Phone	**Extension (if applicable)**		

Authorized Official Information

Name _____

Title _____

Organization (if different from PSO)_____

Phone _____

Extension (if applicable) _____

Email _____

A*lternative* Point of Contact Information

If the Authorized Official will not be the primary point of contact,please provide an alternative primary point of contact below.

NOTE: The Alternative Primary Point of Contact will be copied on all communications from AHRQ and will be shown as the Point of Contact on the Listed PSOs webpage, however, the Alternative Point of Contact cannot make attestations on behalf of the PSO.

Please provide information for the Point of Contact below:

Name _____

Title _____

Organization _____

Phone _____

Extension (if applicable) _____

Email _____

PART II: INFORMATION AND ATTESTATIONS REGARDING ORGANIZATION AND STRUCTURE

1.	Are all of the attestations previously 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", you are attesting that the PSO remains in compliance with all of its prior attestations and the applicable requirements of sections 3.102(b) and 3.102(c). *If the answer is "No", please explain the changes in an attachment to this certification form.*	___ Yes ___ No
2A.	Do you attest that the entity seeking listing is not a health insurance issuer; a unit or division of a health insurance issuer; or an entity that is owned, managed or controlled by a health insurance issuer? *Definition from section 3.20 - Health insurance issuer means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in 42 U.S.C. 300gg–91(b)(3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of 29 U.S.C. 1144(b)(2)). This term does not include a group health plan.*	___ Yes ___ No
2B.	Do you attest that the entity seeking listing is not any of the following: - An entity that accredits or licenses health care providers; - An entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; - An agent of an entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; - An entity that operates a Federal, state, local, or Tribal patient safety reporting system to which health care providers (other than members of the entity's workforce or health care providers holding privileges with the entity) are required to report information by law or regulation.	___ Yes ___ No
3.	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 occurs subsequent to revocation, expiration, or voluntary relinquishment of a listing of or by a PSO. *If the answer to question 3 is "Yes," please provide here the name of the entity or entities that the Secretary declined to list or delisted.* **Name of Denied Entity/Delisted PSO**:	___ Yes ___ No
4.	Have any of this PSO's officials or senior managers held a comparable position of responsibility in an entity that was denied listing or a PSO that was delisted?	___ Yes ___ No
5.	Will the PSO promptly notify the Secretary during its period of listing if it can no longer comply with any of its attestations or the applicable requirements in sections 3.102(b) and 3.102(c)?	___ Yes ___ No
6.	Will the PSO promptly notify the Secretary during its period of listing if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes?	___ Yes ___ No

7.	Is the PSO a component of another (parent) organization according to the definition in section 3.20? *If the answer to Question II.7 is "Yes," please proceed to Part III.* *If the answer to Question II.7 is "No," please proceed to Part IV.*	___ Yes ___ No

PART III: INFORMATION AND ATTESTATIONS FOR COMPONENT ORGANIZATIONS

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

Contact information for all of the PSO's parent organization(s) must be provided. To determine whether the component organization seeking listing has one or more parent organizations, review the definitions of each of these terms in section 3.20. If the PSO has more than one parent organization, the PSO must provide the name and all other contact information specified in this section for each additional parent organization in an attachment to this certification form.

Parent Organization Information

Name

Is the parent organization a legal entity?	___ Yes ___ No
Does the parent organization have an alternate legal name? *If the answer to this question is "Yes", please provide the name on the line below* _____	___ Yes ___ No
Do you have any changes to the contact information for the PSO's parent organization on file with AHRQ? *NOTE: If the answer to this question is "Yes," provide the updated information below.*	___ Yes ___ No

Address

Phone	Extension (if applicable)

Website Address		
Is there any other organization meeting that definition of parent organization for the component PSO that is not already on file with AHRQ as a parent organization of the PSO? *NOTE: If the answer to this question is "Yes", use an attachment to provide information about the new parent organization. Contact* pso@ahrq.hhs.gov *with any questions.*		__Yes __No
1.	Is the component entity an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity?	___ Yes ___ No
As certified below, do you attest that the PSO is (a) currently complying, and (b) will continue to comply throughout the period of continued listing, with each of the additional requirements for component organizations (items 2 through 6) below:		
2.	Maintaining patient safety work product (PSWP) separately from the rest of the parent organization(s) of which it is a part and establishing appropriate security measures to maintain the confidentiality of PSWP?	___ Yes ___ No
3.	Maintaining PSWP in an information system in which the component PSO does not and will not permit unauthorized access by one or more individuals in, or by units of, the rest of the parent organization(s) of which it is a part?	___ Yes ___ No
4.	Requiring 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
5.	Ensuring that the pursuit of its mission will not create a conflict of interest with the rest of its parent organization(s)? *NOTE: For a component PSO of a parent organization that is subject to mandatory U.S. Food and Drug Administration (FDA) reporting requirements under the Federal Food, Drug, and Cosmetic Act and its implementing regulations (e.g., drug, device, and biological product manufacturers), "conflict of interest" includes a particular scenario. Such component PSO must ensure that its mission will not conflict with its parent organization's compliance with its obligations as an FDA-regulated reporting entity, including reporting certain information to the FDA and providing FDA with access to particular records.*	___ Yes ___ No
6.	Is the PSO's parent organization(s) one or more of the following types of entities excluded from listing as a PSO? (See section 3.102(a)(2)(ii)) *If the answer is "No", skip to Part IV.* *If "Yes", check all that apply and proceed to question 7:*	___ Yes ___ No

	❑ An entity that accredits or licenses health care providers; ❑ An entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; ❑ An agent of an entity that oversees or enforces statutory or regulatory requirements governing the delivery of health care services; or ❑ An entity that operates a Federal, state, local or Tribal patient safety reporting system to which health care providers (other than members of the entity's workforce or health care providers holding privileges with the entity) are required to report information by law or regulation.	
7.	Has the PSO included a statement with this form outlining the role and scope of authority of the parent organization(s) as required by section 3.102(c)(4)(i)(A)?	___ Yes ___ No

8.	Does the parent organization(s) that is excluded from listing have policies and procedures in place that would require or induce providers to report PSWP to the component PSO?	___ Yes	___ No
9.	Will the component PSO notify the Secretary within five calendar days if the parent organization(s) that is excluded from listing adopts such policies or procedures that would require or induce providers to report PSWP to the component?	___ Yes	___ No
10.	Does the PSO acknowledge that the adoption by the parent organization(s) excluded from listing of policies or procedures that would require or induce providers to report PSWP to the component PSO during the PSO's period of listing will result in the Secretary initiating an expedited revocation process in accordance with section 3.108(e)?	___ Yes	___ No
11.	Has the component PSO prominently posted notification on its website and published in any promotional materials for dissemination to providers, and will the component PSO continue to prominently post on its website and publish in any such promotional materials, for each parent organization excluded from listing, a summary describing its parent organization's role, and the scope of the parent organization's authority, with respect to any of the following that apply: Accreditation or licensure of health care providers, oversight or enforcement of statutory or regulatory requirements governing the delivery of health care services, serving as an agent of such a regulatory oversight or enforcement authority, or administering a public mandatory patient safety reporting system, as required by section 3.102(c)(4)(i)(C)?	___ Yes	___ No
12.	Does the PSO prohibit, and will it continue to prohibit, the sharing of staff with the parent organization(s) excluded from listing, as set forth in section 3.102(c)(4)(ii)(A)?	___ Yes	___ No
13.	Are any written agreements between the component PSO and any individuals or units of the rest of	___	___

	the parent organization(s) excluded from listing limited to, and will any such future written agreements be limited to, only those units or individuals of the parent organization(s) whose responsibilities do not involve the activities specified in paragraph 3.102(a)(2)(ii), i.e., accreditation or licensing of health care providers; oversight or enforcement, including as an agent, of statutory or regulatory requirements governing the delivery of health care services; or operation of a Federal, state, local or Tribal patient safety reporting system to which health care providers are required to report information by law or regulation?	Yes No

PART IV: ATTESTATIONS REGARDING PATIENT SAFETY ACTIVITIES AND PSO CRITERIA

Attestations Regarding Patient Safety Activities

As certified below, do you attest that the PSO is (a) currently performing, and (b) will continue to perform throughout the period of continued listing, each of the required patient safety activities (1-8 below) below:

1.	Carrying out efforts 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, or information regarding best practices?	___ Yes ___ No
4.	Utilizing PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk?	___ Yes ___ No
5.	Maintaining procedures to preserve confidentiality with respect to PSWP?	___ Yes ___ No
5B.	Do the written confidentiality policies and procedures include and provide for compliance with the confidentiality provisions of subpart C of 42 CFR Part 3?	___ Yes ___ No
5C.	Do the written confidentiality policies and procedures include and provide for notification of each provider that submitted PSWP or data as described in section 3.108(b)(2) to the entity if the submitted work product or data was subject to an unauthorized disclosure or its security was breached?	___ Yes ___ No
6.	Carrying out appropriate security measures with respect to PSWP?	__ Yes ___ No
6B.	Do the written policies and procedures include and provide for compliance with appropriate security measures as required by section 3.106?	___ Yes ___ No
6C.	Do the written security policies and procedures include and provide for notification of each provider that submitted PSWP or data as described in section 3.108(b)(2) to the entity if the submitted work	___ Yes ___ No

	product or data was subject to an unauthorized disclosure or its security was breached?	
7.	Utilizing qualified staff?	___ Yes ___ No
8.	Operating a patient safety evaluation system (PSES), and providing feedback to participants in a PSES?	___ Yes ___ No
	Attestations Regarding PSO Criteria As certified below, do you attest that the PSO is (a) currently complying with, and (b) will continue to comply with throughout the period of continued listing, each of the required PSO criteria:	
9.	Conducting activities to improve patient safety and the quality of health care delivery is both (a) the PSO's mission and (b) the PSO's primary activity? A "yes" answer attests that both (a) and (b) are will and will continue to be met.	___ Yes ___ No
10.	Using (a) appropriately qualified workforce members and (b) the appropriately qualified workforce includes licensed or certified medical professionals? A "yes" answer attests that both (a) and (b) are and will continue to be met.	___ Yes ___ No
11.	Having at least two bona fide contracts for the purpose of receiving and reviewing PSWP, each of a reasonable period of time, each with a different provider, within each applicable 24-month period? A “yes” answer attests both that this requirement: a) was met for the 24-month period beginning with the PSO’s date of initial listing, and (b) was or will be met in every sequential 24-month period.	___ Yes ___ No
12.	The PSO is not a health insurance issuer or a component of a health insurance issuer, and it will continue to comply with this prohibition?	___ Yes ___ No
13.	The PSO has made, if applicable to date, and will make disclosures to the Secretary required by section 3.102(d) regarding all providers with which it has a Patient Safety Act contract and any other contractual, financial or reporting relationships that meet the descriptions in paragraphs 3.102(d)(2)(i)(A) through (C)? *NOTE: If the PSO has entered or will enter into any relationships required by section 3.102(d)(2) to be disclosed to the Secretary, the PSO will need to submit a “Disclosure” statement form (Disclosure form link) within 45 days of entering the relationship with the provider in accordance with section 3.112.*	___ Yes ___ No
13.B	The PSO has made, if applicable to date, and will make disclosures to the Secretary required by section 3.102(d) if, taking into account all relationships that the PSO has with any provider with which it has a Patient Safety Act contract, the PSO is not independently managed or controlled, or the PSO does not operate independently from, the contracting provider as contemplated by section 3.102(d)(2)(i)(D)? *NOTE: If the PSO has entered or will enter into any relationships required by section*	___ Yes ___ No

	3.102(d)(2) to be disclosed to the Secretary, the PSO will need to submit a "Disclosure" statement form (Disclosure form link) within 45 days of entering the relationship with the provider in accordance with section 3.112.	
14.	The PSO is using only the Common Formats, as published by AHRQ, for the collection of PSWP (Option I) (available at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview)? *Note: If your PSO uses a combination of AHRQ Common Formats and alternative formats, please answer "No" to 14 and "Yes" to 14B and explain how your PSO uses both in 14B.* *If the answer is "No", please proceed to question 14B.* *If the answer is "Yes," please proceed to question 15.*	___ Yes ___ No
14B.	The PSO is using an alternative system of formats and definitions to collect PSWP from providers that permits valid comparisons of similar cases among similar providers (Option II)? *If the answer is "Yes," please explain how the alternative system permits valid comparisons of similar cases among similar providers in an attachment to this certification form and proceed to question 15.* *If the answer is "No," please proceed to question 14C.*	___ Yes ___ No
14C.	If not using the Common Formats (Option I) or an alternative system of formats and definitions to collect PSWP (Option II), has the PSO included an attachment to this certification form, providing a clear explanation for why it is not practical or appropriate for the PSO to comply with Option I or Option II at this time?	___ Yes ___ No
15.	Using and will continue to use PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk?	___ Yes ___ No

PART V: CERTIFICATION OF ATTESTATIONS

I am legally authorized to complete this form on behalf of the 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 understand that, if during the period of listing there are any changes to the accuracy of the listing information, or if there are any changes in the contact information, the PSO must notify AHRQ by submitting a Change of Listing Information form, or by contacting AHRQ's PSO Office via e-mail at pso@ahrq.hhs.gov or calling toll free at (866) 403-3697 or (866) 438-7231 (TTY).

******This form must be signed and dated by the Authorized Official on record with AHRQ.***

Signature_____

Date_____

This completed form is considered public information.

Burden Statement

This survey is authorized under 42 U.S.C. 299a. This information collection is voluntary and the confidentiality of your responses to this survey is protected by Sections 944(c) and 308(d) of the Public Health Service Act [42 U.S.C. 299c-3(c) and 42 U.S.C. 242m(d)]. Information that could identify you will not be disclosed unless you have consented to that disclosure. Public reporting burden for this collection of information is estimated to average 18 hours per response, the estimated time required to complete the survey. 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. The data provided will help AHRQ's mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable. 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 (OMB control number 0935-0143) AHRQ, 5600 Fishers Lane, Room #07W42, Rockville, MD 20857, or by email to REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.