

Form Approved

OMB No. 0935-0143

Exp. Date: ??/??/20??

PATIENT SAFETY ORGANIZATION: CERTIFICATION FOR INITIAL 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 entities seeking listing as a PSO must certify they meet to become a PSO. 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 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 Health and Human Services."

An entity seeking listing must complete this form, and submit it to AHRQ's PSO Office via email, at psa@ahrq.hhs.gov. To submit a hard copy, please send to: PSO Office, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857. *Entities seeking listing are encouraged to contact AHRQ's PSO Office before submitting this form.*

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 entity name prominently at the top of the attachment.*

PART I: ENTITY CONTACT INFORMATION

Please complete the following information about the entity seeking listing as a PSO, which, if the entity is listed, will be used for the "[Listed PSOs](#)" section of the AHRQ PSO website. If the entity seeking listing is a component of another (parent) organization, the name listed below 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.

Proposed PSO Name	PSO Website Address (If provided, should be accessible upon listing and should link to PSO-specific website or web page)
Will the PSO be a legal entity?	☐ Yes ☐ No
Will the PSO have an alternate legal name?	☐ Yes ☐ No

<i>If the answer to this question is “Yes”, please provide the name on the line below:</i> _____			
Physical Address	City	State	Zip Code
Mailing Address (if different from street address)	City	State	Zip Code
Phone	Extension (if applicable)		
Authorized Official Information When an entity seeks listing as a PSO, it must identify an individual with authority to make commitments on behalf of the entity – referred to as “Authorized Official” or “AO” – to complete certain requirements for listing. See section 3.102(a) and the AHRQ guide, “What is the Role of the PSO Authorized Official?” Name _____ Title _____ Organization (if different from PSO) _____ Phone _____ Extension (if applicable) _____ Email _____ Alternative Point of Contact Information <i>If the Authorized Official will not be the primary point of contact for the proposed PSO, please provide an alternative primary point of contact below.</i> 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 (if different from PSO) _____

Phone _____

Extension (if applicable) _____

Email _____

PART II: INFORMATION AND ATTESTATIONS REGARDING ORGANIZATION AND STRUCTURE

1A.	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? <i>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.</i>	___ Yes ___ No
1B.	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	___ Yes ___ No

	holding privileges with the entity) are required to report information by law or regulation.	
2.	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. <i>If the answer to question 2 is "Yes," please provide here the name of the entity or entities that the Secretary declined to list or delisted.</i> Name of Denied Entity/Delisted PSO:	___ Yes ___ No
3.	Have any of this entity'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
4.	If listed, will the entity 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
5.	If listed, will the entity 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
6.	Is the entity seeking listing a component of another (parent) organization according to the definition in section 3.20? <i>If the answer to Question II.6 is "Yes," please proceed to Part III.</i> <i>If the answer to Question II.6 is "No," please proceed to Part IV.</i>	___ Yes ___ No

PART III: INFORMATION AND ATTESTATIONS FOR COMPONENT ORGANIZATIONS

If the entity seeking listing as a 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 entity'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

If the parent organization have an alternate legal name?

If the answer to this question is "Yes", please provide the name on the line below:

Address

Phone

Extension (if applicable)

Website Address

1.	Is the component entity an FDA-regulated reporting entity or organizationally related to an FDA-regulated reporting entity?	___ Yes	___ No
2.	Will the component entity maintain patient safety work product (PSWP) separately from the rest of the parent organization(s) of which it is a part and establish appropriate security measures to maintain the confidentiality of PSWP?	___ Yes	___ No
3.	Will the information system in which the component PSO maintains PSWP prohibit unauthorized access by individuals in, or by units of, the rest of the parent organization(s) of which it is a part?	___ Yes	___ No
4.	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
5.	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)? 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	___ Yes	___ No

	<i>the FDA and providing FDA with access to particular records.</i>	
6.	Is the parent organization(s) of the entity seeking listing one or more of the following types of entities excluded from listing as a PSO? (See section 3.102(a)(2)(ii).) <i>If the answer is "No", skip to Part IV.</i> <i>If "Yes", check all that apply and proceed to question 7:</i> ☐ 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.	___ Yes ___ No

7.	Has the entity seeking listing submitted 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 organization if listed as a PSO?	___ Yes ___ No
9.	If listed as a PSO, will the component organization 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 entity 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 during the component entity's period of listing, will result in the Secretary initiating an expedited revocation process in accordance with section 3.108(e)?	___ Yes ___ No
11.	If listed as a PSO, will the component prominently post notification on its website, and publish in any promotional materials for dissemination to providers, 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	___ Yes ___ No

	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)?	
12 .	If listed as a PSO, will the entity 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 .	If listed as a PSO, will any written agreements between the component PSO and any individuals or units of the rest of the parent organization(s) excluded from listing 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

Please review the definition of Patient Safety Activities in section 3.20 before completing these items. At the time this form is submitted, the entity seeking listing as a PSO certifies that it has written policies and procedures in place, complete and ready to guide the PSO's workforce in performing each of the eight Patient Safety Activities (items 1-8) required by section 3.102(b)(1) and as defined in section 3.20

NOTE: At the time a PSO seeks continued listing, it must certify that it is performing, and will continue to perform, each of the eight defined patient safety activities.

1.	Does the entity have written policies and procedures in place to carry out efforts to improve patient safety and the quality of health care delivery?	☐ Yes	☐ No
2.	Does the entity have written policies and procedures in place to carry out the collection and analysis of PSWP?	☐ Yes	☐ No
3.	Does the entity have written policies and procedures in place to develop and disseminate information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices?	☐ Yes	☐ No
4.	Does the entity have written policies and procedures in place to utilize PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk?	☐ Yes	☐ No
5.	Does the entity have written policies and procedures in place to maintain 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.	Does the entity have written policies and procedures in place to implement and maintain 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 product or data was subject to an unauthorized disclosure or its security was breached?	☐ Yes	☐ No
7.	Does the entity have written policies and procedures in place to ensure the utilization of qualified staff?	☐ Yes	☐ No

8.	Does the entity have written policies and procedures in place to perform the activities related to the operation of a patient safety evaluation system (PSES), and to the provision of feedback to participants in a PSES?		
Attestations Regarding PSO Criteria Please review the criteria in section 3.102(b)(2) before completing these items. As certified below, the entity seeking listing as a PSO attests that, if listed, it will comply throughout its period of listing with each of the seven required PSO criteria for listing (items 9-15) in section 3.102(b)(2).			
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.		
10.	Will the entity have (a) appropriately qualified workforce members and (b) will the appropriately qualified workforce include licensed or certified medical professionals? A "yes" answer attests that both (a) and (b) will be met.		
11.	Will the entity have 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 24 months of its date of initial listing (and meet that requirement in every sequential 24-month period)?		
12.	Does the entity attest that it is not a health insurance issuer or a component of a health insurance issuer, and that it will continue to comply with this prohibition?		
13.	Will the entity make the 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 entity is listed and enters 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.		
13. B	Will the entity make the 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 entity is listed and enters 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.		
14.	Will the entity collect PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers to the extent practical and appropriate? NOTE: The Secretary has provided common definitions and reporting formats, known as Common Formats, which are available at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.		
15.	Will the entity use PSWP for the purpose of providing direct feedback and assistance to providers to		

Yes No

effectively minimize patient risk?	
------------------------------------	--

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 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 email at psa@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.